Consideration of the Human Factor in the Design and Development of a New Medical Device: Example of a Device to Assist Manual Ventilation

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Abstract: The human factor is often critical in the performance and safety of a large number of medical devices. To minimize risks to users and patients, health authorities have reinforced their requirements including human factors and usability testing during the development of new technologies. Human factors engineering (HFE) is an interdisciplinary approach to evaluating and improving use safety, efficiency, and robustness of work systems. The new device should be tested to show its safety and effectiveness for the intended users, uses and use environments. In order to fulfill these regulatory requirements, international standards suggest implementing the User Centered Design process during the technology design and development lifecycle. We would like to present here a case study of a HFE plan about an ongoing medical device development in order to illustrate how to practically process; then we will present some more general considerations on HFE development for medical devices.

Manual ventilation is an essential step in the resuscitation of respiratory distressed patients. It must be carried out adequately so as not to worsen patient's condition. This technique has its advantages but also risks such as excessive insufflated pressures resulting in pulmonary barotrauma and gastric insufflation. In fact, many studies have shown that manual ventilation practices are far above recommended guidelines. Several solutions have been proposed by some manufacturers to achieve better control over manual ventilation parameters, but none has really convinced the medical community to date. Thus we propose to develop a new technology guided by a well adapted HFE.

We first carried out a study with the existing material to observe the practices of 140 professionals in several clinical situations on an artificial lung, allowing to reproduce situations of respiratory deficiency and to record the parameters. The preliminary results showed a fairly low rate of manual ventilation performance with high ventilation rates, confirming the fragmented data of the literature on the subject. Thus, with the help of a local company, Polycaptil, we developed a new medical device, with an algorithm for real-time analysis on the basis of the 54,000 ventilatory cycles recorded during our study. After the prototype reached the technical objectives and demonstrated good reliability, we organized a usability validation test with 40 end-users. After the ventilation tests, participants were asked to complete a survey on the ease of use of the prototype, including the ergonomics of the entire system, the human-machine interface and its main functions.

Both usability surveys provided important guidance for the development of the final device. Finally, the human factors validation testing should be realized during a prospective clinical trial of the first use in humans of a device for monitoring manual ventilation.

The human factor is one of the most differentiating characteristics of the development of a medical device compared to the development plan of a drug. Specific methodologies are being developed and adapted tools have been set up. Based on our example, methods and purposes of HFE evaluation will be described at every stage of the device development lifecycle in order to sensitizing designers of new technologies.

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1 INTRODUCTION

The human factor is often critical in the performance and safety of a large number of medical devices. Multiple cases were reported on side effects such as patient harm or death due to misconception or misuse of medical devices (Jans 2016), for example overdoses with drug pen injectors (Schertz 2011), radiation damages during radiotherapy (Ash 2007), or deaths associated with implantable cardioverter defibrillator (Hauser 2004). These observations have led to a growing interest in the effect of the human factor on medical device use outcome (BSI 2016, Xuanyu 2015).

The introduction of any new method requires a learning curve of varying length. The dexterity of the users explains in part the variability of operator performances observed with a new medical device. The clinical benefit may not only depend on the medical device itself or on the operator, but also on the performance of the medical team, on the new organization of the actors and on the technical platform available. These organizational changes and their repercussions must be considered when introducing a new medical device into an existing technical and human environment. The diversity of intended users and the possible changes between them (physician, healthcare professional, patient, natural caregiver, etc.) requires the development of a particularly "intuitive" use of some medical devices, such as, for example, automated external defibrillators which are supposed to be usable by anyone anywhere, or almost. Studies of the human-machine interface, human-machine interactions, and usability have thus become essential in the development of a number of medical devices.

Thus, to minimize risks to users and patients, health authorities have reinforced their requirements including human factors and usability testing. In the US, such testing is required for manufacturers to provide the FDA with validation of control and prevention of use-related risks for new or modified devices for their intended use (FDA 2016). In Europe, "ergonomics" essential requirement for CE marking was enhanced in the latest EU revised Medical Device Directive (2007/47) (European Parliament Council 2007) and emphasized in the future 2017 European Rules on Medical Devices. Human factors engineering (HFE) is an interdisciplinary approach to evaluating and improving use safety, efficiency, and robustness of work systems. Thus, the Human Factors and Ergonomics Society propose several definitions of human factors and ergonomics so that the reader can see how different groups vary in their use of the terms (HFES 2016). Nevertheless, a valuable definition from an industrial point of view is driven by regulatory agencies. Human factors engineering is defined by the FDA (FDA 2016) as: "*The application of knowledge about human behavior, abilities, limitations, and other characteristics of medical device users to the design of medical devices including mechanical and software driven user interfaces, systems, tasks, user documentation, and user training to enhance and demonstrate safe and effective use.*" For the FDA, the Human factors engineering and usability engineering can be considered to be synonymous (FDA 2016). The new device should be tested to show its safety and effectiveness for the intended users, uses and use environments. In order to fulfill these regulatory requirements, international standards suggest implementing the User Centered Design process during the technology design and the development lifecycle (IEC 2007). The User Centered Design process is an iterative design and evaluation strategy which involves end-users as well as recipient by taking into account their needs and by including them in design and evaluation activities (ISO 2010).

We would like to present here a case study of a HFE plan about an ongoing medical device development in order to illustrate how to practically proceed; then we will present some more general considerations on HFE development for medical devices.

2 EXAMPLE FOR A DEVICE

2.1 Context and Issues

Respiratory distress is frequently encountered in emergency situations. Providing enough oxygen and removing carbon dioxide from the patient with respiratory failure and / or in cardiac arrest is an important emergency procedure, and in this respect, manual ventilation is always used as a first aid by rescuers. Manual ventilation is an essential step in the resuscitation of anesthetized or respiratory distressed patients. It must be carried out adequately so as not to worsen patient's condition. However, the implementation of adequate manual ventilation is difficult even when performed by experimented health professionals (Busko 2006, Elling 1983, Martin 1993, Wynne 1987). Although this technique has its advantages its drawbacks are excessive insufflated pressures resulting in pulmonary barotrauma and gastric insufflation. In fact, many

studies (Bergrath 2012, von Goedecke 2005, Cooper 2006) have shown that manual ventilation practices are far above recommended guidelines from the European Resuscitation Council, or American Heart Association, or the French Society of Anesthesia & Critical Care. "*Ventilation during Cardio Pulmonary Resuscitation is usually overzealous. Both emergency medical personnel and in-hospital resuscitation teams have been shown to deliver artificial breaths at rates far exceeding the published recommendations*" (Cooper 2006). Professional rescuers were observed to excessively ventilate patients during out-of-hospital Cardio Pulmonary Resuscitation. Subsequent animal studies demonstrated that similar excessive ventilation rates resulted in significantly increased intrathoracic pressures and markedly decreased coronary perfusion pressures and survival rates. Some investigations in animals have shown that a significant reduction in respiratory rates from 30 to 12 cycles / min could lead to an increase in the survival rate from 14% to 86%. Several solutions have been proposed by some manufacturers to achieve better control over manual ventilation parameters, such as insufflation or leakage volumes, but none has really convinced the medical community to date.

2.2 Study of Practices for the Conception of Device Design

We first carried out a study with the existing material (Laerdal and Ambu balloons) to observe the practices of professionals on an artificial lung, enabling to reproduce clinical situations of respiratory deficiency and to record the parameters (frequency , insufflated volume, leaks) during ventilation (Khoury 2016).

140 professionals (anesthesiologists, emergency workers, firefighters, paramedics, nurses, physicians,) were asked about the difficulties encountered in manual ventilation and then ventilated a lung simulator (ASL5000 - Ingmar Medical®) by sequences of 5 minutes under different conditions.

The preliminary results showed a fairly low rate of manual ventilation performance with high ventilation rates, confirming the fragmented data of the literature on the subject. The main reason advanced by health professionals was the lack of feedback: "we do not know what we are doing". The importance and the necessity of this feedback was confirmed by a study by Bowman et al. which showed the interest of the visualization of the insufflated volumes by a significant improvement of 47% in ventilation performances (Bowman 2012).

The control of this manual ventilation is an important challenge for health professionals and clearly shows the need to develop a device to help with the use and to control this ventilation.

The results of our study and the clinical practice guidelines enabled us to define the expected specifications for a new product. This product should be a medical device inserted between the balloon and the mask (or the endotracheal tube) in order to provide rescuers with some feedbacks, whether on the delivered and expired volumes, or on the ventilation rate.

Thus, with the help of a local company, Polycaptil, we developed a new medical device, the VEDIAS system, with an algorithm for real-time analysis of the manual ventilation. The 54,000 ventilatory cycles recorded during our study were used as the basis for the development of this algorithm.

2.3 Simulated-use Testing on Prototype

Several prototypes of assistance to manual ventilation have been developed and evaluated on bench-test. After the prototype reached the technical objectives and demonstrated good reliability, we organized a usability validation test with end-users.

40 health professionals (egalitarian stratification on hospital origin or not) were randomly selected from the initial 140 volunteers. The goal of this simulated-use testing is to evaluate the performance of the new prototype in the bench conditions similarly to the first study. Thus, there is a study of usability and technical validation of the pre-final prototype.

The ventilation tests were performed with both a ventilation mask and a tracheal tube for 5 minutes each time. After the ventilation test, participants were asked to fill in a survey on the ease of use of the prototype, including the ergonomics of the system, the human-machine interface and its functions.

Both usability surveys provided important guidance for the development of the final device. Firstly, the device has been effective in regularizing manual ventilation in accordance with the recommendations of the learned societies (see figure 1).

The results obtained showed a very clear improvement in the ventilation rate increasing from 15 to 90% with the use of the prototype, (in press).

The device was considered relevant in the

management of patients with dyspnea or cardiorespiratory arrest: 97.5% of participants found it to be useful for the management of artificial ventilation. The display of following items: bar graph, ventilatory parameters and alarms appeared to be relevant to at least 95% of the participants, although some doctors have suggested additional parameters that will be considered for future development of the device.

The human-machine interface was easy to use and intuitive, and the screen ensured sufficient visibility for 97.5% of the participants. However, 25% of users felt that the weight and size of the device could be detrimental to the practice and a great effort has been made to design the final product.

Considering the users' feedbacks, reinforced by the very high improvement of their performances, the prototype has evolved towards a demonstrator that can be used for the first-in-man clinical trials.

Nevertheless, other usability studies will be necessary, firstly during the clinical feasibility study focusing on the handling and taking into account of the information transmitted by the device (video recording to be done), and secondly during the pivotal study to integrate certain environmental conditions of the emergency (stress, fatigue, behavior of others, parasitic noises, meteorological situations, luminosity etc.).

2.4 From the Concept to the Product

The next figures (figure 2, 3 and 4) show the progress of conception from the computer-aided design to the redesigned version after the feedback from users in tests.

2.5 Human Factors Validation Testing

The human factors validation testing should be realized during a prospective clinical trial of the first use in humans of a device (the demonstrator) for monitoring manual ventilation. This study will have three objectives:

- *Evaluate and compare intra-individual variability of vital parameters between ventilator and manual ventilation (with or without the device)*
- *Evaluate the reliability and accuracy of the ventilatory parameters measured by the device*
- *Obtain a "reasonable assurance" of the security of the device*

This study will take place in the operating room under stable conditions. During this phase, the device will be connected between the respirator and the endotracheal tube to study the reliability and accuracy of the ventilatory parameters measured relative to those displayed on the respirator. Then the intubated patient will be ventilated manually

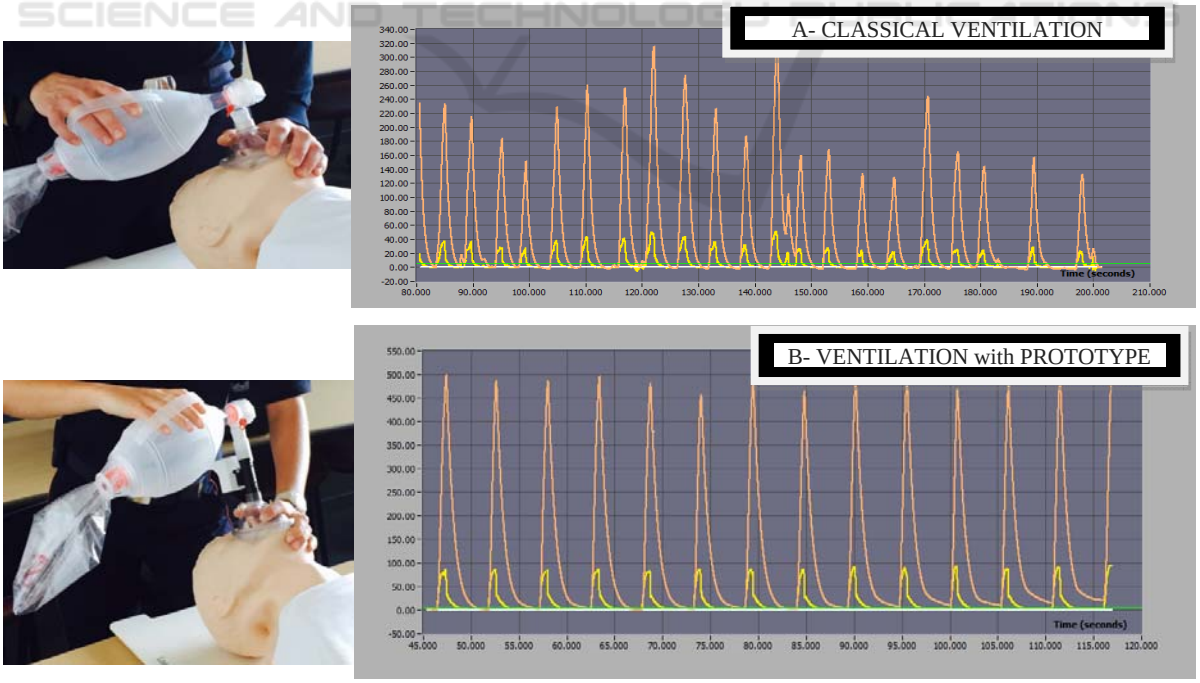

Figure 1: Comparison of ventilation cycle (orange: tidal volume, yellow: airway pressure) without (A) and with (B) our prototype.

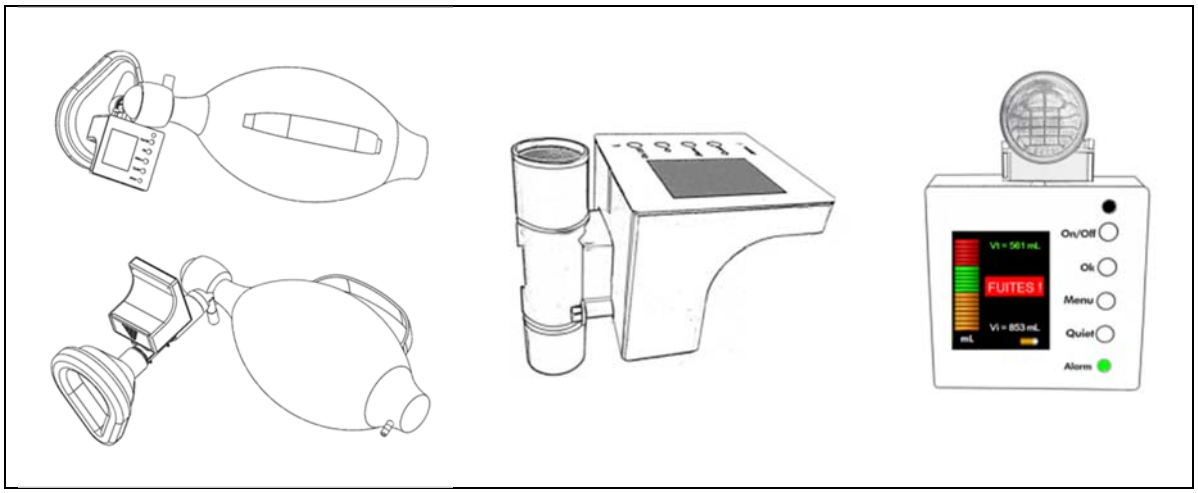

Figure 2: First stage of conception by Computer-aided design.

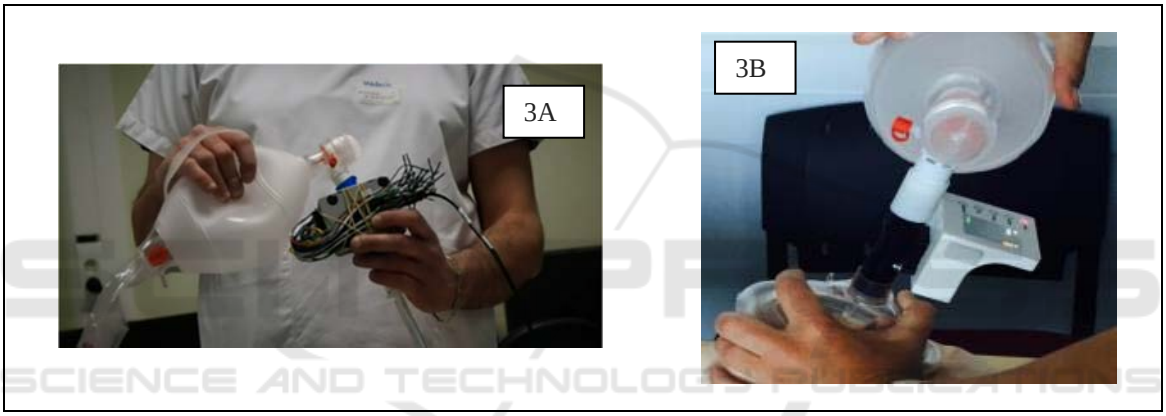

Figure 3: Second stage of conception with scalable prototyping (3A: first prototype, 3B: operational prototype for end-user tests).

Figure 4: Final stage of conception with demonstrator (4A: device alone, 4B: device in place between the mask and the balloon).

manually with an Ambu® Spur® II self-filling balloon by the anesthesiologist either with the device or without the device for minutes. During this phase, the anesthesiologist will be blinded in relation to the hemodynamic parameters of the patient displayed on the multiparametric scope. Another physician will continuously monitor the hemodynamic parameters of the patient and will judge the need to discontinue the study at any time. The tank of the balloon will be connected to an air / oxygen mixer to obtain a FiO2 equivalent to that of the respirator. The hemodynamic parameters will be recorded continuously. The anesthesiologist will use bag-valve either according to his habits (occurrence without the device) or according to the indications given by the device.

The main criterion for the efficiency of manual ventilation will be the value of the End Tidal Carbon Dioxide (EtCO2), which is a parameter for monitoring the ventilation of intubated patients and under general anesthesia, very sensitive to the change in minute volume (current volume x ventilatory frequency). If this value is outside the recommended range (between 35 and 45), the manual ventilation will be considered a failure and the patient will be put back under the respirator (before the end of the 10 minutes ventilation). The secondary parameters will be oxygen saturation (SpO2), heart rate (HR) and systolic blood pressure (SBP).

At the "demonstrator" stage, clinical studies are genuine "clinical trials" with specificities to be taken into account such as reproducibility, learning curve, human-machine interface, etc. The major risks would be poor patient ventilation if the instructions provided by the medical device to guide the act of ventilation are not used correctly by the healthcare professional. The video equipment of the used operating rooms will allow continuous video recording centered on the handling of the new device.

The expected benefit is a regular and efficient ventilation of the patient during the period of manual ventilation thanks to the intuitive use of a new device to guide ventilation.

This study will allow the finalization of the technical and regulatory documentation to get the CE marking of the product in order to be launched on the market. Subsequently, a demonstrative clinical trial (multicenter prospective randomized controlled trial) will be in actual condition of use with a view to social security coverage and reimbursement.

3 DISCUSSION

The presented usability studies relate to the same product at a different stage of development. Since medical device must be used quickly, under highly stressful conditions, and possibly by inexperienced healthcare professionals, it was crucial to design and develop a product that incorporated HFE, risk analyses, and actual testing of user-device interaction without training. They were made necessary in relation to the very operator-dependent characteristic of the performance of the gesture with the existing materials, attested by literature and our results with a sample of 140 health professionals. Here we have the glaring example of the importance of the human factor in the performance of the act. As a result, several usability studies are required, as well as a reproducibility study and a fine analysis (by video recording) of the handling of the apparatus and of the reactions of the professional to the information communicated by the latter. Several prototypes are then made using the «feedback» systematically analyzed in each of the studies.

The human factor is one of the most differentiating characteristics of the development of a medical device compared to the development plan of a drug. Specific methodologies are being developed and adapted tools have been set up in several centers (living lab, simulation center, rapid prototyping platform, fab-lab etc.) whose certification is obtained or in progress.

The Human factors validation testing is included into a first in man clinical study with a demonstrator to verify the functionalities of the device in stable clinical situations. The experimental design is a comparative intervention study on the one hand with the "gold standard" constituted by a respirator and on the other hand the reference device in practice for the same final purpose (manual ventilation). At this stage of development, the judgment parameters analyze the technical performance of the apparatus: technical sensitivity, accuracy, reliability, reproducibility of the measurement, functions claimed (in this case stability of ventilation and provision of ventilation according to standards).

HFE validation studies, such as those performed here, have some limitations: the tests were simulation tests rather than real clinical practice use, and the study design of the validation studies was more observational rather than interventional. In addition, safety data other than outrange frequency rate and excessive volume were not captured. However, the HFE validation studies were designed to demonstrate optimal user–device interactions, and

the simulation testing conducted here is defined as an acceptable method for assessing safe and effective use of a new medical device according to regulatory requirements.

It is important that HFE studies are adequately representative of the real-world setting. This was achieved by simulation of the anticipated use environment, and testing the performance of users to ventilate patients with the device.

Human behavior in the medical device context involves interaction with it in the environment of use: not only related to device control, but also because of the wrong medical device being prescribed at the wrong time for the wrong type of patients. Tools supporting human–device interaction can greatly improve the care that patients receive, and increase their engagement in their care. However, these tools also need to support the user (e.g., patient, health-care provider, caregiver). This is particularly important for lifesaving devices, such as manual ventilation, that require situational awareness, management, and interaction.

Human factors methods have been developed in many different fields such as aeronautics for decades and have appeared in the medical field for medical devices mainly at the beginning of the sixties last century, and really after year 2000.

HFE addresses multiple aspects on how the medical device is used, for whom, by who, under what conditions, and in what environments. The goal of HFE is "*to optimize the relationship between humans and systems by studying human behavior, abilities, and limitations and using this knowledge to design systems for safe and effective human use*" (Gawron 2006).

HFE includes multiple steps and follows an iterative process during the device lifecycle (Gosbee 2002). Along with risk assessment, an essential part of the HFE process involves assessing the interactions between the users and the device in an environment that mimics the real-world experience of the user. HFE evaluation focuses on four main purposes depending on the stage of the device development lifecycle:

1/ Conception of the Device Design. The FDA recommends that HFE be applied early as possible in the design process to allow for the most efficient, purposeful, and optimal product design possible, ensuring safe and effective use. An important first step includes qualitative studies on end-users needs with interviews and observation of the real-world tasks actually performed in the intended-use of the new device. Sometimes called "Cognitive walk-through" or "think aloud", this evaluation encourage participants to explain any difficulties or concerns they have (FDA 2016). In parallel, risk management plan and performing use-related risk analysis (failure modes and effects analysis) should be started (FMEA 2011).

2/ Optimization of the Prototypes. A formative evaluation consists of iterative and fast simulated-use testing of safety and performances of early mock-ups and prototypes up to the pre-final version of the device. Risks mitigation should be one of the primary focus for device optimization, to eliminate or reduce potential harm to the user (AAMI 2013). This kind of testing involves systematic collection of data from test participants using a device, device component or system in realistic use scenarios but under simulated conditions of use (FDA 2016). Thus, HFE may affect product design (e.g., handling, buttons, covers, threshold and type of alarms) to allow for optimal and safe use and appropriate device functions.

3/ Validation of Premarket Device. A summative HF evaluation generates the validation of the usability of the final version of the product before its release for clinical use. Human factors validation testing is generally conducted under conditions of simulated use, but when necessary, human factors data can also be collected under conditions of actual use or as part of a "first in man" clinical investigation.

4/ Post Market Surveillance. This is a part of the "clinical evaluation plan" claimed for the CE mark, and included in the risk management plan in US. Data could be collected within direct observation, users' questionnaire or interview, or review of incidents reports. The safety follow up is performed through database like MAUDE (Manufacturer and User Facility Device Experience) including declaration by manufacturers, device user facilities, health care professionals, patients or consumers. Usability feedbacks could improve new version of the product.

4 CONCLUSIONS AND PERSPECTIVES

Our examples show the feasibility of HFE for medical device development,.

The development stages of medical devices from the idea to the market can include, from the outset, clinical studies according to the "predictability of the action" of the device. If this is not obvious, or does not correspond to a known function, then a clinical

proof-of-concept study of the benefit of this function may be necessary.

The study of the actual need by observing existing practices and pathophysiology studies can contribute to the proper design of the new device by providing the relevant technical specifications for the product specifications. These data would reinforce the interest of the new device in its "preclinical" file.

Risk analysis of the product should systematically include usability data.

A "performance analysis" should include study of the learning curve, inter- and intra-operator performance variability, potential misuse, and in general the implications of the human factor, in addition to "pure" technical performance.

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