

PRODUCT DESIGN FOR THE HEALTH SECTOR: USABILITY ISSUES IN EMBEDDING TRACING TECHNOLOGIES IN SURGICAL INSTRUMENTS

Alvaro M. Sampaio^{1,2}, Miguel Terroso¹, António J. Pontes², Ricardo Simoes^{1,2}

¹ School of Technology, Polytechnic Institute of Cávado and Ave,
Campus do IPCA, 4750-810 Barcelos, Portugal

msampaio@ipca.pt, mterroso@ipca.pt, rsimoes@ipca.pt

² Institute for Polymers and Composites IPC / I3N,

University of Minho, 4800-058 Guimarães, Portugal
msampaio@dep.uminho.pt, rsimoes@dep.uminho.pt

Abstract

Surgical instruments are a major asset and a significant share of the total capital spending of a hospital. It is therefore important to track the product inside the health provider's facilities and when it temporarily leaves them. One of the technologies available to face this problem is RFID. Nevertheless, there are many challenges in incorporating an RFID tag in surgical instruments. Aside from technical issues, it is vital to ensure that the tag placement does not hamper the performance of the health professional using the instrument.

Therefore, the aim of this work is to develop a polymer-based product that features an embedded RFID, and which can be physically coupled to surgical instruments, while simultaneously ensuring the user requirements listed. For this purpose, usability tests have been conducted with surgeons using different physical mock-ups, and the results have been benchmarked as input for concept selection among different solutions.

In this paper we describe the methodological process employed, from initial design through physical mock-ups tests, in a context of rapid development. The same methodology can be replicated for the development of other products for the healthcare sector, where technical requirements and specifications are very strict and where adoption of new technology is highly dependent on the opinion of healthcare professionals.

Introduction

When producing medical devices, the manufacturers must design them to fit their intended purpose not only in design, manufacture and finish, but also by selecting adequate materials. For surgical instruments, generally only stainless steel (hardened, non-rusting) can meet the tough requirements in terms of tenacity, rigidity, blade characteristics, wear resistance, and corrosion resistance. Surgical instruments are a major asset and represent a significant share of

the total capital spending of a hospital. Typically, they have high unit cost compared with many other industries. It is therefore important to be able to track the product as it moves along the supply chain. Equally important is to track the product inside the health provider's facilities.

One of the technologies being considered by many industries to face these problems is RFID. This technology involves electronic tags that emit radio signals and devices called readers that pick up the signal. This method of auto-identification can be used to communicate seamlessly with components, products and assets in the supply chain. It has the potential to revolutionise the global supply chain, logistics and inventory management. Unlike the bar-code, this technology will eventually network physical objects without human intervention, and operate seamlessly throughout the environment. Thus, it features high potential use for tracking surgical instruments.

Nevertheless, the case of incorporating an RFID in surgical instruments is not trivial, namely:

- 1) the environmental conditions, as tag reliability can be affected by humidity, metal surfaces, and other factors. Also, current RFID tags cannot withstand extreme temperatures without temperature-resistant housing,
- 2) insuring that the placement of the RFID tag poses absolutely no threat to the patient, nor does it hamper or limit the performance of the health professional using the surgical instrument.

Therefore, one of our goals is the development of a product that features an embedded RFID, and can be physically coupled to surgical instruments.

Problem Statement

Defining a problem is not a trivial task. It is necessary to frame it adequately within a context and to establish well-defined boundaries. One of the main issues in defining a problem is where to set those boundaries. They will affect not only the methods that can be used to solve the problem, but also the outcome. The problem boundary is essentially defined by the product design requirements. Thus, selection of adequate requirements is paramount. There are two aspects

to this: first, selecting which product design requirements need to be set and understood, and second, which should be their values (specifications).

The number of specifications can range from the lower limit of having no specifications at all, which we will term totally unconstrained design (TUD), to the upper limit of having a very high number of specifications (for perspicuity sake, we shall theoretically consider a infinite number), which we term totally constrained design (TCD). Real problems can be found almost anywhere in the range between TUD and TCD.

A different issue is whether the problem is defined by providing a framing question (or set of questions) to be answered, or indicating the desired solution (or set of solutions). The former has a clear focus on the problem itself, whereas the later focuses on the outcome. Also, one can say that the former can lead to solution with a much wider range of characteristics than the later. Meaning, when working from questions one can go in almost any direction, and eventually come up with a totally unforeseen and unexpected solution, whereas when desired solutions are an input of the problem, they cannot vary as significantly.

These two different issues, TUC vs TCD, and problem definition based on questions vs solutions, can be better discussed by defining a domain space for specifications. This is shown in Figure 1.

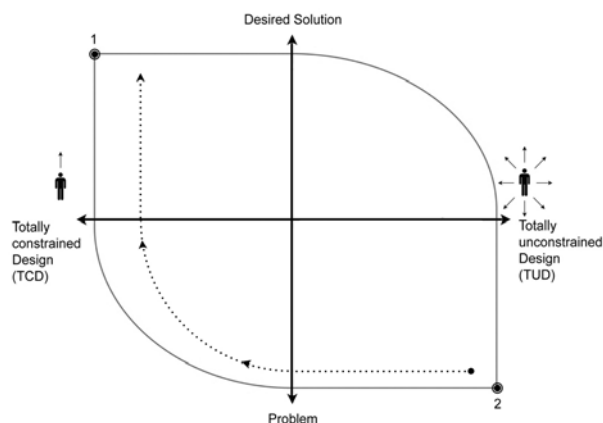


Fig. 1. Product Design boundaries

In Figure 1 we illustrate our argument that a significant area of the domain space is inaccessible by the very essence of TCD and TUD. Namely, problems defined by the desired solution(s) cannot enable highly unconstrained design (towards the limit of TUD). This results from the fact that defining the desired solution(s) already implies setting some boundaries in the form of specifications. However, there are no limitations to constrained design. In the very limit, a problem can be in point 1 of the domain space,

where a very limited number of solutions are possible (one could argue that theoretically it would tend to one single possible successful outcome).

Conversely, problems defined by the question(s) to be answered are incompatible with highly constrained design. In order to have a broad scope in the approach to the problem, one cannot impose many constraints. Thus, it is easier to have highly unconstrained design for this type of problem definition. In the very limit, a problem can be in point 2 of the domain space, where a very high number of solutions are possible (one could argue that theoretically it would tend to an infinite number of possible successful outcomes).

In the Product Design and Development (PDD) process described in this paper, one of the most important issues was to understand the real necessity and, of course, to clarify the problem. In the beginning, the necessity is only very generically understood. We start this investigation with a problem that needed to be clearly defined before progress could be made. It has been widely recognized that problems are ill-defined [1], because they are not completely determined. However, the goal of the first steps must be to evolve from an ill-defined problem in a TUD, to a desired solution with the framing constraints of TCD. These framing constraints have to ensure safety, efficiency, and all other desired aspects of the problem.

In the case-study described, this is particularly important, as health facilities are environments where human error can result in tragedy, including the loss of lives. As such, changes or improvements to medical devices, protocols or procedures must be carefully studied [2]. Thus, the initial stages of the PDD process must incorporate a careful analysis of the needs as well as usability issues.

Understanding the problem

For the purpose of the first stages of the PDD process, the employed methods rely on Ethnographic Research, and Voice of the Customer. Ethnography, in general terms, is the description of a social group based on the observation of their behaviour in their own environment. In PDD processes, problems and their full discovery is a difficult task and a imperative for success. As such, ethnographic research is a powerful method, as it permits defining and understanding the users, how they interact, what they want, their perceptions and their behaviour. Through this method, it is possible to find needs that were hidden and understand the impact of a product in a specific context of use. By applying this method to our case-study, we

develop a strong understanding of the overall cycle of surgical instruments and not only in the operating room. More specifically, we begin to understand how many people are involved in that cycle, what are the procedures and steps, safety measures and different ways of handling the instruments. More important, we have defined the role of each user and established their importance.

The second method – Voice of the Customer (VOC) – is a technique to identify what the users truly want from the product. Since requirements tend to be linguistic and non-precise in nature, Voice of the Customer is employed to translate the 'needs and wants' to 'product features' and further along into process and production planning aspects.

The surgical instruments cycle

Surgical instruments require significant attention inside a health provider organization such as hospitals. Aside from the typically large number of surgical instruments that a hospital has, they represent an asset normally associated to the most difficult procedures. These devices, far from their general use, have a very distinct cycle that involves lots of people. If, from a general point of view, it can be said that a major preoccupation with these devices are problems that have already been acknowledged and involve, for example, leaving instruments inside human body [3], in a more specific approach, the number of people that interact directly with these instruments and the different places where they are used, are important issues and makes tracking of the surgical instruments a complex but necessary task.

The overall cycle of the Surgical Instruments (SI) (Figure 2) has ten main Zones (A to J) divided in two key facilities – the Sterilization Unit (SU) and the Operating Room (OR). Three distinct individuals interact in this cycle and in different zones, the scrubbing nurse (1), the surgeons (2) and the sterilization technicians (3).

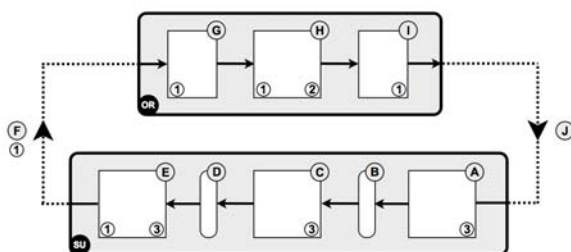


Fig. 2. Overall cycle of Surgical Instruments

In Zone A, SI arrive in bags from the OR covered in blood. Sterilization technicians count the SI and proceed to cleaning with several operations that involve water and ultrasonic cleaners. After this procedure, SI are placed in

washer disinfecting machines (Zone B) that can go up to 70 °C. The connection from zone A to C is made through the washer machine, so distinct sterilization technicians work in these zones. Zone C is where SI are counted and matched to each set. This is a very time-consuming task, since several records have to be made. Following the identification of the SI, sets are prepared and sealed to go to the autoclave (Zone D). As in the case of the connection between Zone A to C, Zone C connects with E through the autoclave (Zone D). In this last zone of the SU, sets are stored by sterilization technicians.

When a surgical procedure is necessary, the OR needs to be prepared. This is one of the tasks of the scrubbing nurses. They are responsible for picking the sets need for the procedure from the storage in the SU. This task involves direct communication with sterilization technicians and a pick-up registration for management operations concerns. Between the storage (Zone E) and the OR (Zones G to I), is a Zone (F) that differs from hospital to hospital, and it can range from just a door in the same corridor, to a different floor (stairs or elevator), to another building block in the hospital grounds. In zone G of the OR, scrubbing nurse prepare the surgical table that consists in dividing several sets and grouping then by types of SI. After this procedure, starts the counting of the SI. When the OR is prepared, the surgical procedure can begin (Zone H), with the SI being delivered from the table by hand from the scrubbing nurse to several surgeons and back again. The scrubbing nurse needs to count the SI instruments once in the middle of the surgery. In the end (Zone I), and for security measures, the patient only leaves the OR when the scrubbing nurse finishes the counting of the SI. Still in this zone, several SI are placed in a bag in an arbitrary way. The last Zone is in the connection from the OR to the SU (Zone J). This Zone varies from hospital to hospital, namely, the persons involved. That can be the scrubbing nurse, the sterilization technician or other.

Requirements and specifications

In order to prevent accidents in the operating room, strict protocols are implemented in healthcare providers, since the scrubbing nurse needs to perform the counting of the surgical instruments before, during and after surgical procedures. This task is, obviously, difficult, error prone, and very time-consuming. For the problem of knowing to which set or department a SI belongs, hospitals normally put a sticker in the instrument (Figure 3).



Fig. 3. Sticker in a Surgical Instrument

Although this is a common procedure in hospitals, it has many problems, including cleaning the device - stickers need to be removed in every cycle, which is made more complex due to the glue. Also, the stickers only allow identification inside the cleaning and sterilizations facilities. As it can be seen, this is too time-consuming and ineffective solution. Another aspect is that currently, it is near-impossible to tell how many times a surgical instrument has been used. For security reasons, individual management of the surgical instruments need to be performed, so the issue of tracking becomes much more than just a question of preventing accidents, and also a way to reduce task times, optimize nurse efforts, and manage the number of uses of each instrument.

Since several users become part of the overall cycle in different facilities, it was necessary to understand the users' needs for each facility and task. In figure 4 one can see the 'needs and wants' of the several users, divided in usability issues and technical issues in the two different facilities. This figure was set up with the VOC technique, so specifications were set for each need. The technical issues rely mainly on the performance and capacity of RFID technology, and create the specifications for the communication tag. The technical issues are centered in the procedures that are needed to perform and are not specific of any user. So they are core technical needs of the cleaning and sterilization tasks, coupled with regulations and standards applicable to these medical devices.

Facilities	User / Process	Needs and wants	Specifications
SU - Sterilization Unit	Sterilization technician	Usability Issues	
		Fast counting of SI	RFID – Individual placement
		Fast Identification SI	RFID – Color tag
	Scrubbing Nurse	Easy to Clean	*
		Usability Issues	
		Fast identification of sets	To RFID
	Overall procedures	Easy registration pick-up	To RFID system
		Technical Issues	
		Water resistance	Water proof
		Ultrasonic Wave resistance	20-40 kHz
OR – Operating Room	Scrubbing Nurse	Shock resistance	Falls and friction
		Thermo-resistance	160°C
		Pressure resistance	1.5 Kg/cm ²
	Surgeon	Usability Issues	
		Fast counting	RFID – Individual placement
		Safety	*
	Overall procedures	Usability Issues	
		Safety	*
		Non intrusive	*
		Technical Issues	
		Regulations and standards (Medical devices)	UE Directive 2007/47/CE Decreto- Lei n.º145/2009 (Portuguese) MEDDEV 2.12/1

Fig. 4. Needs and their corresponding specifications by user and facility

On the other hand, usability issues are of course more narrowed by the user. 'Fast counting' and 'fast identification' are easily identified needs and also those easily analyzed. The first can be met with individual placement of RFID tags, while the second can be attempted by ensuring the RFID is colored, similarly to the color striker already in use. Obvious, validation will be later required to check whether the visual identification is accurate or the RFID information needs to be used. After the development of the needs list, the major concerns concern in the difficulty of some specific usability requirements (Marked with *, in figure 4).

These needs are 'easy to clean', since blood is a liquid and it can infiltrate narrow places. And the most important requirements: 'Safety' – necessity to be fully aware that any device coupled to SI cannot in any circumstance fall off during a surgical procedure, and 'Non-intrusive', since surgeons are not open to changing any of their usability protocols.

So, although the major improvement in coupling a microelectronic device will be seen in the performance of the scrubbing nurse and on the sterilization technician, surgeon procedures and requirements were validated as the most important from the performed analysis.

Specifying the objectives

In the surgical instruments case, the main objective is to improve the efficiency of the overall cycle, modifying the procedures of the scrubbing nurse and the sterilization technician in a transparent way without compromising the usability protocols of the surgeons. To achieve that purpose, we need to develop the product in a user-centred design (UCD) methodology. UCD has been characterized by the ISO 13407 [4] as the development of products with a direct link with users, the knowledge of their needs to perform an appropriate definition of functions between users and technology. To face the user needs and to improve the user-product interaction is, unquestionably, a core activity in PDD processes. Several methods and techniques have been developed to manage this complex process [5]. This is the case of Participatory Design, a method to bridge the gap between users and designers and to centre the attention not just in knowing and understanding the user but also in involving the user in the PDD process.

Saying that, there is no doubt that the direct participation of the different users, more specifically surgeons, in the first phases of the PDD process were paramount. Understanding the problem and the definition of the specifications with the users is a key aspect in the rapid

development of the product, since in all the phases the user becomes part of the development team.

This human-centered methodology based on participatory design led us to refine our initial understanding of the problem. In addition, the revised definition of objectives will ensure that the product being developed will not only match the explicit users' needs but will be in tune with the implicit ones.

Therefore, the revised aim of the case-study became the development of a product that features an embedded RFID and can be physically coupled to surgical instruments without interfering with the surgeon's established usability protocols. The main task became to develop a product that can be coupled to a large part of existing surgical instruments, at the very least all instruments contained in a generic set such as that shown in Figure 5.



Fig. 5. Surgical instruments generic set

The developed product will allow for a fast and accurate count during surgical and sterilizing operations, and, at the same time, knowing the number of uses of each instrument, as well as the specific set to which the instrument belongs (since several sets can be used in just one surgery, with the SI mixed at the end). This system will prevent several typical errors, such as miscounting, misplacement, and accidental disposal of instruments, as well as allowing for full traceability of the instruments.

Concluding Remarks

This paper describes a study on the early stages of a PDD process, illustrated through a case-study on traceability of medical devices. The study considers how to understand the real needs of users, how to better define the problem from its initial ill-defined state, and how to extract product specifications from that analysis.

This was achieved by carefully analyzing the problem and its context using the methods of Ethnographic Research and Voice of the Customer. Final users were involved in the process from start, in a User-Centered Design

approach. In the case of product design for the health sector, this is a particularly important feature. Since, as stated by Zenios [p.22 in 6] "When you talk to physicians, as well as others involved in the delivery of care, you've got to learn the difference between what they say, what they want, what they'll pay for, and what they actually do", using a UCD methodology based in participatory design can improve the PDD process in terms of success and time.

We find the described methodological approach can be a powerful tool if adequately employed, and it can ensure a more effective and rapid development of new products. From this approach and the resulting product specifications, an RFID-enabled add-on product to enable the tracking of surgical instruments was designed. That product is currently in the final development stage and will allow automated, none-line-of-sight inventory, meeting the requirements of the surgical environments and the needs for product traceability.

Future work will include the expansion of the described study to the other stages of the PDD process, and the validation of the developed product through usability tests by healthcare professionals.

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Keywords

Product design; Product usability; RFID; Surgical instruments; User-Centered Design; Participatory Design

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