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PRODUCT DESIGN AND DEVELOPMENT OF PRODUCTS WITH EMBEDDED MICROELECTRONICS – SURGICAL INSTRUMENTS TRACEABILITY

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ABSTRACT

Health care providers have been continuously increasing their interest in tracking products. The plethora of goods that they need, the number of persons involved and the enormous space that they have makes an imperative to manage and control everything. As surgical instruments are a major asset and represent a significant share of the total capital spending of a hospital it makes their tracking a necessary task. In this framework we present the major issues of tracking these devices and the developed method to overcome this type of problems in the product design and development process.

INTRODUCTION

For the case of tracking assests, health care providers are labeling all products with technologies that can range from bar-coding to RFID. The benefits of the use of RFID can go from increased productivity to cost reduction (Hodges and McFarlane 2005). However, the great variety of products (shapes, materials, etc) limits their adoption (Deavours et al. 2005). In some cases, the existing products are fully optimized and any changes, as little as they can be, are impossible. This is the case of surgical instruments.

THE DESIGN APPROACH

Since incorporating an RFID in surgical instruments is not trivial, since humidity, metal surfaces and temperature can affect the tag reliability and the devices is a product fully optimized, our first approach to achieve a solution was the development of a polymer-based add-on product that features an embedded RFID, and could be coupled to the original product (surgical instruments).

The product design process required for the case of the surgical instruments unquestionably requires a detailed analysis of the shape, size, and other physical and functional characteristics of the devices. Only in this way it becomes possible to develop the product with the embedded technology to be coupled to the surgical instruments (Sampaio et al. 2010). Another issue is involving the end-user in the development process. Health care facilities are environments where human error can result in tragedy, including the loss of lives.

Placing a novel feature in surgical instruments (such as an externally coupled product) needs to be very carefully considered, as surgical proceedings cannot be modified easily, nor can these modifications to the surgical instruments hamper the way surgeons handle them. In this framework, we have developed a method (solid black rectangles in Figure 1) that allowed us to investigate the two major aspects of the product development process that did not exist in any of the usual product development processes:

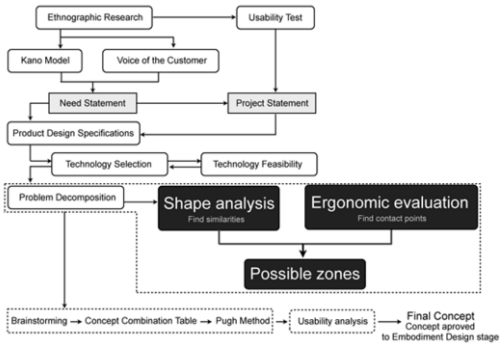

Figure 1: Design process flow

a) We investigated the shape and functional features of all surgical instruments in a generic surgical instruments set, in order to find similarities and common geometries. This shape analysis was developed with Geomagic Qualify software where several areas and combinations of the instruments were match and measured (Figure 2).

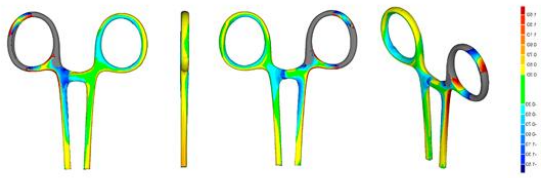

Figure 2: Shape analysis of a needle holder

b) Understanding exactly how surgeons use surgical instruments. In this case an ergonomic evaluation was developed to investigate the contact points between the surgeons hands and the surgical instruments. In this framework, we have conducted a survey with 54 surgeons to discover the contact points with 7 different types of surgical instruments (Figure 3).

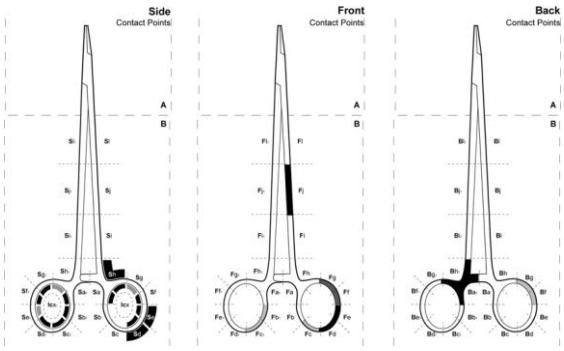

Figure 3. Ergonomic evaluation in a needle holder

The shape analysis provided us with the knowledge on where to grab the add-on product in a possible universal solution and, in the same way, finding out how surgeons grab the instruments will provide insight about neutral zones, the possible zones where the add-on can be attach. Both studies allowed us to establish which areas of the instruments were candidates for coupling an external component.

CONCLUSIONS

With this method it was possible to establish the likely areas to couple the add-on on the SI. The match of the data of the two procedures (Shape analysis and ergonomic evaluation of contact points) was the final aim result pretended. Future work includes prototyping parts, with the embedded RFID tag, and usability tests.
The developed product should 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. This system can help prevent several typical errors, such as miscounting, misplacement or the accidental disposal of instruments.

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