Ergonomics and Design in Healthcare: a Multifactorial User-Centred Approach to Biomedical Assistive Devices

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***Abstract*—One of the new challenges in HealthCare product development is to join design and technology to have no more only reliable but also easy-to-use devices. Up to now product design starts when electronics has been fixed and as small as possible; but in some case miniaturization is negative, especially when elderly or disabled will be the final users. We present a method mixing User Centered Design with technology-driven approaches that allows designers to participate early-on in the process and facilitates the compliance of the patient to device usage. This is a crucial aspects in a perspective of diffusion of biomedical technologies aiming at exploiting the EU vision of Personal Health System for an active responsibility also of end-users in the management of his/her own health and wellbeing. In this scenario usability drives the technology acceptance thus the fast prototyping techniques (both for hardware and software layers) represent an extraordinary tools to integrate technological and user need and to facilitate the product development.**

I. Introduction

HealthCare Product Design, and in particular the development of bio-electronic devices for diagnosis and monitoring, is usually very complex because it concerns many different disciplines (e.g. Medicine, Electronics, Computer Science, Product Design, etc.). Moreover Healthcare products are almost always used by many different actors: caregivers, physicians, patients and their relatives. This implies great difficulties during the design of new products because it is necessary to consider many different points of view, in particular without forgetting the different users' needs.

Healthcare products can be structured as the sum of two components: the back-end and the front-end layer. The first allows the device to work reliably and efficiently, but, the second is related to user's acceptability and functioning, so it is probably the most important characteristic to avoid usage errors. As the two layers are strongly related, their parallel development is needed in order to test each development step with final users.

	Back-end Layer (Engineering development)	**Front-end Layer** (Interaction design)
Hardware	• Electronic Design • Structural Product Design • CPU programming	• Product Design • Haptic interfaces
Software	• Protocols • Signal processing	• Graphic User Interface

Fig. 1. The macro-components to be considered in Biomedical Device design.

In this paper we present the approach we developed in a integrated engineering+design experience in biomedical device design for elderly users, but that could favorably applied in several situations, in particular when unskilled users from the medical point of view are involved. This represent the methodological reference background which drive all our works in progress.

II. Methods

A. Ethnography and Concept design

According with Martin (2008), "medical devices are technology driven rather than resulting from an identified un-meet need". For this reason in the set-up phase of the process, the definition of a complexity map is absolutely necessary; we define this step as "problem". The problem is defined by marketing or by the medical team as the result of everyday work experience. Then the multidisciplinary design team has to define the requirements of the system and to select fixed specifications.

In our method two teams develop side-by-side the back-end and front-end layers of the system. According with technical requirement, Back-end component is developed by engineers and Front-end concept is designed according to the user needs collected directly from in-field ethnographic observations.

After the first integration through fast prototyping, is it possible to involve expert users in tests aiming at redefining the fixed points. As the first prototype could be significantly different of the final product, only expert user can test the results at this stage.

As said before only the methodologies of "Oz Wizard" or Fast Prototyping (with some real functions working) could support this step to obtain significant information about concept assessment. Usually paperboard prototypes, foam or wood mock-ups are used to evaluate anthropometrics interaction in order to define general characteristics and dimensions of the packaging. Evaluating physiological aspect, as range of movement, the importance of the product weight and the accessibility of commands is also possible. Storyboards or movie scenarios (video prototyping) could be used to present a complex situation in order to immerse the user in a virtual context before evaluate the interaction with models. These kinds of tools are particularly used in service design.

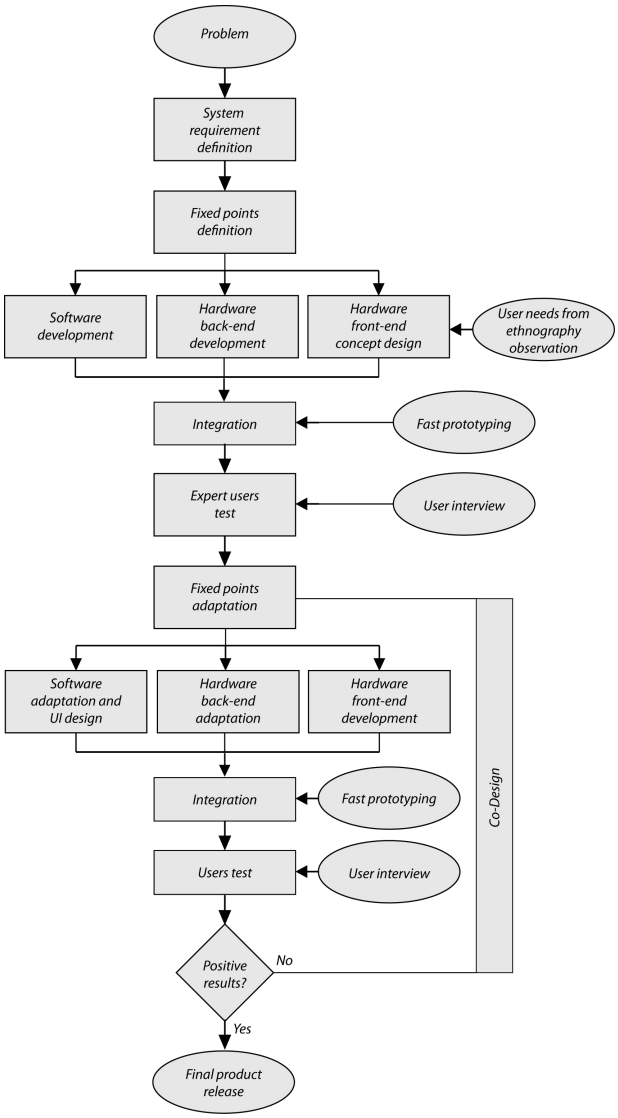

Fig. 2. Flow-chart description for multidisciplinary approach.

B. *Prototype refinement through Co-Design*

In a second step, the front end prototype is developed through 3D Modeling and physical prototypes can be built with rapid prototyping techniques (e.g. ABS printer); Graphical User Interfaces (GUI) can be simulated easily. Normally almost a final product can be obtained and this makes possible to evaluate also the physical/mechanicals issues of the product in a normal condition of use. Those prototypes can already contain electronic circuits and boards and the test are performed directly in-field (Erdmann at al. 1971). Also the user interfaces is almost complete: LEDs, buttons and connectors are built at this level of realization, while colors and icons could be integrated in a very short time even if not in their final configuration. Thus, in this advanced stage, it is easier to evaluate also cognitive and psychological aspects of the user-product interaction thanks to the availability of a well detailed prototype.

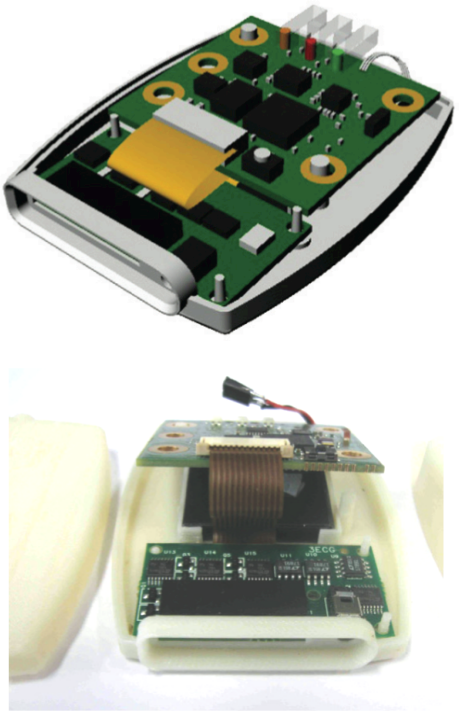

Fig. 3. Example of the 3D model render and its ABS 3D print.

III. Results

We expect that by applying such a method could be possible to reduce the time-to-market of HealthCare products and to have a significant improvement of positive acceptation of product by the users. By applying the method we also obtain longer modifiability of product and earlier user involved capabilities at the same time.

Using fast prototyping techniques from the early steps of product design process is fundamental, especially in healthcare field, where usability can strongly affect safety during clinical processes (diagnosis, monitoring, etc.) and errors in these issues are not acceptable by definition. Rapid prototyping is basically an analysis technique through which the designer can rapidly discover the true and complete set of formal and functional requirements for a proposed product. In classical product development, the user usually cannot view rough physical representation of the final product until the testing phase; this is critical in projects with very long development times results in a very low probability of producing an acceptable product. Nonetheless “all that glitters ain't gold!”; the wrong use of Fast Prototyping can bring to worse result than classical development, there are in fact some risks the user can fall:

- Mistake concepts of rapid prototyping concerning

definitions, objectives and correct application of technique;

• Disagreements with users and customers regards methodology, standards, tools and so on;

• Out of order test user who want to interact and evolve a prototype into a system that does everything for everyone all of the time;

• Budgets slashes and efforts shortcuts dictated by the word “fast”;

• Premature delivery of a prototype indeed of final;

• Over fitted prototype substituting elegance and efficiency for flexibility.

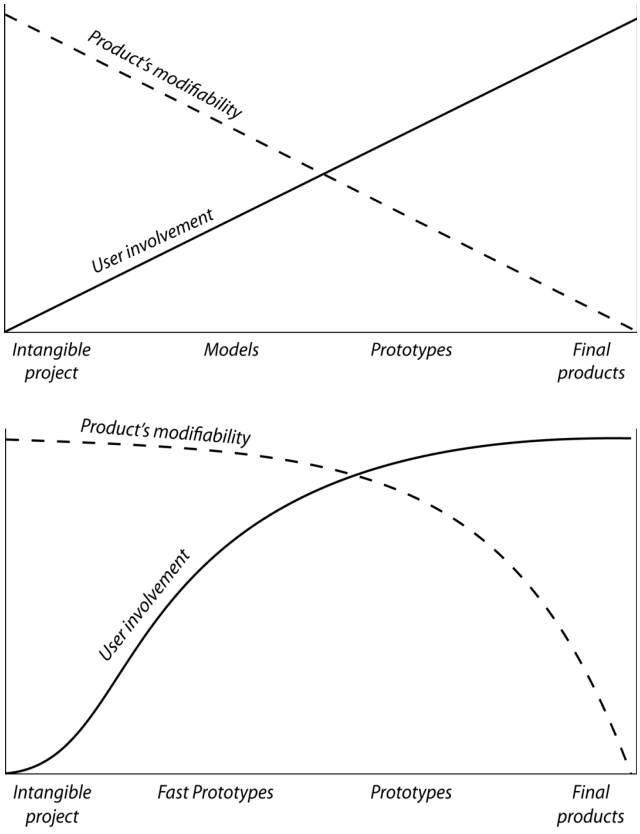

Fig. 4. Curves of User Involvement, Modifiability and project price by not applying (up) or by applying (below) the proposed method.

IV. Conclusion

The future of healthcare is based on new technologies and systems for a more accurate and personalized anywhere diagnosis, treatment of pathologies and quality of care. To achieve his goal, the management and coordination of health services for the whole range of services, from primary to tertiary care, must undergo radical structural changes. Welfare and education of citizens have become primary elements which also produce the effects of prevention and early diagnosis, with the need to offer care services outside hospitals, in the sphere of everyday life. The ambitious objective is to enable health services reliable, efficient, economic and interactive, in any place at any time to anyone (Lymberis and Gatzoulis, 2006).

The introduction of these new ways of delivering care services needs also that citizen / patient should have a more central role. Self responsibility is fundamental, but it is strictly related to easy-to-use- biomedical technologies implementing these services.

Telemedicine should be no more an eternal promise but an effective framework: the ongoing experiments to develop and validate new services and / or processes should become reality. Only in this way we can meet the main macroeconomic challenges regarding the expectation of citizens to receive high quality services, demographic changes with the aging population, increasing the prevalence of chronic diseases and increasing health expenditure (Doughty et al. 1996). In this context, the role of technological innovation is strategic and fundamental.

The introduction of tools for anticipating user involvement and tests could produce a significant improvement in both time-to-market, and user satisfaction together with costs and resources savings. User compliance and patient’s device acceptability are increased too. Going towards a home care and monitoring future of the clinical assistance, only through this kind of process new technologies can be successfully introduced in healthcare practice.

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