UNIVERSITY OF SÃO PAULO

ESCOLA DE ENGENHARIA DE SÃO CARLOS

DEPARTAMENTO DE ENGENHARIA DE PRODUCÃO

Mapping of the purposes of using prototypes in new medical products projects

Cursework presented to São Carlos' Engineering School of University of São Paulo for obtaining the title of Electrician Engineer.

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SÃO CARLOS

2017

A474m Anselmo Silveira Lima, Mayra
Mapping of the purposes of using prototypes in new medical products projects / Mayra Anselmo Silveira Lima; orientadora Janaína Mascarenhas Hornos da Costa; coorientadora Thiago Bertolini dos Santos. São Carlos, 2017.

Monografia (Graduação em Engenharia Elétrica com ênfase em Sistemas de Energia e Automação) -- Escola de Engenharia de São Carlos da Universidade de São Paulo, 2017.

1. Prototyping. 2. Usability. 3. Electromedical devices. 4. ABNT NBR IEC 60601-1-6 standard. 5. User experience. I. Título.

FOLHA DE APROVAÇÃO

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Título: "Mapping of the purposes of using prototypes in new medical products projects"

Trabalho de Conclusão de Curso defendido e aprovado em 28 / 11 / 2017,

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RESUMO

O equipamento médico é essencial para diagnóstico, tratamento e monitoramento clínico de pacientes. É devido à sua extrema importância para a sociedade que a produção industrial nos cuidados de saúde cresceu significativamente, conforme registrado pela Associação Brasileira da Indústria de Artigos e Equipamentos Médicos, Odontológicos, Hospitalares e de Laboratórios (ABIMO). A importância da usabilidade dos aparelhos eletromédicos é ratificada pelo fato de que um equipamento defeituoso pode levar a situações comprometedoras para a saúde dos pacientes. Isso, no entanto, pode ser evitado através do controle de riscos decorrentes da utilização de aparelhos eletromédicos, o que pode ser realizado pelos fabricantes ao longo do Processo de Desenvolvimento de Produto (PDP) através de prototipagem. O PDP é uma sequência de tarefas de processamento de informações, durante a qual a falta de avaliação do projeto pode acarretar inúmeros problemas. Entre eles, destaca-se a falta de usabilidade, não atendendo assim às necessidades dos usuários e prejudicando a interface entre o software e eles. O objetivo da avaliação de prototipagem realizada nesta tese é identificar possíveis falhas no serviço ao usuário, garantindo assim a provisão de aparelhos totalmente seguros. Ao aumentar o compromisso com os estágios de prototipagem dos aparelhos elétricos, os erros são minimizados, a satisfação subjetiva do usuário é assegurada e, além disso, as despesas com a implementação do produto podem ser mitigadas. Há diversas formas de iniciar-se o processo de desenvolvimento de um determinado produto, mas independente da escolha da metodologia a ser utilizada, a prototipagem é fundamental para a otimização de tempo e esforço empregados no projeto. Para isso, a estratégia ideal consiste na identificação do contexto de uso do aparelho e das exigências de usabilidade da interface. Implementando-se a estratégia de prototipagem nas etapas iniciais do PDP, reduz-se o risco de falhas e retrabalhos no projeto, além de o produto corresponder às expectativas e necessidades dos usuários. A prototipagem contribui, portanto, para a avaliação da usabilidade do aparelho, o que é crucial para a otimização do processo de desenvolvimento e implementação do mesmo.

Palavras-chave: prototipagem, usabilidade, aparelhos eletromédicos, norma ABNT NBR IEC 60601-1-6, experiência do usuário.

ABSTRACT

Medical equipment is essential for the diagnosis, treatment and clinical monitoring of patients. It is due to its extreme importance for the society that industrial production in health care has grown significantly, as registered by the Brazilian Association of Medical-Dental equipment Industry (ABIMO). The importance of usability of electro-medical appliances is ratified by the fact that defective equipment can lead to compromising situations for patients ' health. This can, however, be avoided by controlling risks of using electro-medical appliances. This must be carried out by manufacturers in their product development phase, through prototyping; the goal of the prototyping evaluation carried out in this thesis is to identify possible user-service failures, thereby ensuring the provision of fully secure appliances. By increasing commitment to prototyping stages of electrical appliances, errors are minimized, user' satisfaction is assured and, in addition to this, implementation expenses can be mitigated. Prototyping assist, therefore, in evaluating the usability of the apparatus, which is crucial for the optimization of time and effort employed in the project.

Keywords: prototyping, usability, electromedical devices, ABNT NBR IEC 60601-1-6 standard, user experience.

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1 INTRODUCTION

Clark and Fujimoto (1991) interpret the Product Development Process (PDP) as a sequence of information processing tasks. The lack of user perspective evaluation during the development of a certain product may cause numerous problems, including lack of usability. This may result in not meeting users' needs and decreasing the quality of the interface between the software and them. According to Bogers and Horst (2014), by increasing the effort in prototyping, which can be sorted according to what the prototype explores or to its results, errors can be minimized and users' satisfaction might be enhanced. In addition, implementation costs may certainly be attenuated.

There are several ways of initiating the development process of a certain product. Despite the methodology to be used, according to Hall (2001), prototyping is essential for time and effort optimization employed in the project. The optimal strategy for this consists in the identification of the usage context of the apparatus and the required usability interface. By implementing the strategy in the early stages of the PDP, the risks of failure and rework are reduced in the project and the product is more likely to meet users' expectations and needs. Furthermore, it is important that an evaluation of the impacts is done so that it can, coupled with the PDP stages, be analyzed in the future and support in action plans (HALL, 2001).

This undergraduate thesis aims to analyze the different types of prototypes generated during the development of electromedical products designs, together with the benefits and challenges due to the utilization of prototyping. Through literature review, different types of prototypes used for medical equipment were identified. For analyzing the improvement of devices interfaces it was also collected papers regarding usability and the involvement of users during the product development.

In order to achieve the objective of this work, a survey was elaborated to be applied in companies listed in Hospitalar repository. The survey was based in Forza (2002) methodology and followed the steps: theoretical literature review, design of the survey, pilot test, data collection, data analysis and reporting. The details of the methodology and sample of the survey are presented at the results section.

2 LITERATURE REVIEW

2.1 Importance of prototypes

The Product Development Process (PDP) is, according to Clark and Fujimoto (1991), a sequence of information processing tasks such as strategy, organization, concept generation, marketing plan creation, evaluation, and commercialization of a new product. The process begins with generating an idea and defining a concept, and finishes with the product's introduction to the market. The lack of user perspective evaluation during its development may cause, according to Bogers and Horst (2014), numerous problems, including lack of usability; which will not meet users' needs and may decrease the quality of interface between the software and them. The word prototype comes from the Latin words *proto*, meaning original, and *typus*, meaning form or model. In a non-technical context, a prototype is an especially representative example of a given category. By increasing the effort in the prototyping activities, errors can be minimized and users' satisfaction might be enhanced; in addition, implementation costs may certainly be attenuated (BOGERS & HORST, 2014).

The lack of evaluation of products during their development can cause numerous issues, such as lack of usability and a consequent non-fulfillment of users' needs. It is therefore essential that new products meet a specific need and work and communicate properly, and this can only be assured by a well-planned development. New products fail because (1) there was no basic need for the item; (2) the new product did not meet the established needs, considering all disadvantages and (3) the new product did not properly communicated (marketed) to the intended user (CRAWFORD, 2010).

Poor design can cost companies money directly through attending to user calls for service and complaints and through returned goods; it can also indirectly cost through reduced sales because of poor consumer acceptance and poor product image, and through the associated follow-on effects of consumer perceptions of the company itself. This is becoming especially so with the advent of embedded computer processors in the so-called “smart" domestic consumer products (HALL, 2001).

The advent of embedded computer processors in the so-called “smart” domestic products, for example, facilitates an increase in the functionality of a product but often to the detriment of its usability. Norman (1988, apud Hall, 2001) calls this phenomenon creeping featurism and suggests that the complexity of use increases as the square of the increase in functionality. Technology is becoming smaller and smaller but at the same time with more programmable functions and other market-driven features.

Size reduction usually imposes physical constraints on the design of the user-technology interface according to Hall (2001). This can lead to problems in use through small, multi-modal buttons and, at the same time, only limited visual feedback in small, and often, non-backlit LCD displays. However, other examples of consumer technology which have sufficiently large, physical interfaces are not always immune from usability problems. For example, some public transport, automatic ticket vending machines have been shown to be very poorly designed (ADAMS & HALL, 1992, apud HALL, 2001). Different evaluation methods should be chosen according to the output that is required: errors, performance times, usability, design and others (HALL, 2001). This thesis focuses, however, on standard usability evaluation methods.

According to page 4 of the standard 62366: 2010 “Usability engineering application for health products" of Brazilian Technical Standards Association – ABNT, usability is the user interface characteristic that establishes effectiveness, efficiency, easy of learning and user satisfaction." A product is therefore considered usable if the intended users can achieve their goals with effectiveness, efficiency and satisfaction in a specific context of use. Issues caused by lack of usability, such as utilization errors, poor design and implementation problems, additional costs and final users' dissatisfaction rectify how important usability is in a product development.

According to Bogers and Horst (2014), prototyping translates usability problems into design changes and it detects emerging usability problems through active engagement and experimentation. The typical software usability department has never before had such a golden opportunity to take a lead role in product development. Enabled by vigorous focus on software usability and the availability of a number of robust prototyping tools, significant positive contributions are being made to software development through software prototyping (RUDD; ISENSEE, 1991). If done systematically, prototyping provides the means to model software applications to support the evaluation of design alternatives early in the product development cycle. According to Rudd (1996), the experiences of designers in developing and evaluating user-interface prototypes provide testimonials regarding the many applications and benefits of prototypes.

Iterative design promotes the refinement and optimization of interfaces through discussion, exploration, testing, and iterative revision (RUDD; STERN; ISENSEE, 1996). A project's development process describes the flows of work among development phases and the completion of development tasks within each phase. The characteristics of a development process describe the relative difficulty of development activities, concurrence relations among activities, delays within processes such as defect discovery and iteration within and between phases. According to Crawford (2010), the phases of a New Product Process are as follow:

1. Opportunity identification and selection
2. Concept generation
3. Concept/project evaluation
4. Development
5. Launch

2.2 Utilization of prototypes

During the first phase of the Product Development, opportunity must be identified and selected, directing the developers to where they should look at; this leads the PD to its second phase, when initial review occurs to evaluate whether the idea is worth screening or not. If the idea is validated, it comes to the third phase of the PD, which includes a full screen of the concept / project evaluation, when it has to be decided if it should be developed or not. The fourth phase is the development of the product, characterized by a progress report, when questions such as "have we developed the product?" and "if not, should we try it?" must be answered so that the product may finely be launched. This corresponds to the fifth and last phase of the PD, when market is tested and so are its strategies. (CRAWFORD, 2010)

In product development, users often remain unknown until the product is marketed (KUJALA, 2008). Keil and Carmel (1995, apud Kujala, 2008) confirmed by their survey that more successful projects employed more direct links to users and customers than did less successful projects. Users play therefore an important role when it comes to evaluating certain forms of mock-ups and prototypes, in sufficient fidelity, in order to get early feedback concerning usability. According to Preece et al. (1994, apud Hall, 2001), evaluation is defined as the context of designing the interaction between humans and computers, as particularly being concerned with gathering data about the usability of a design or product by a specified group of users for a particular activity within a specified environment or work context". As part of the design process, it is necessary to evaluate designs iteratively using representative users performing appropriate tasks or work, within specific environments or work contexts. This process of user testing of design prototypes is generally called prototyping. (HALL, 2001)

Early use of prototyping concentrated on the physical aspects of design (e.g.: layouts and workstation dimensions), but as computer technology became more widely available, prototypes could be easily and quickly developed on computer screens (METZ, RICHARDSON & NASIRUDDIN, 1997; WRIGHT & MONK, 1989; VIRZI, PENN, TULLIS & GREENE, 1990; BLATT & KNUTSON, 1994; HALL, ZINSER & KELLER, 1999, apud HALL, 2001). This has facilitated the ability to conduct the so-called rapid prototyping, either in the form of software interface storyboards with hypermedia tools or computer-controlled production of 488 R. R. HALL solid form models of products, which allow the look and feel attributes of a product to be evaluated.

Prototyping can take many forms and be carried out for many purposes. Jordan (1998, apud Hall, 2001) states that “there are a number of different prototyping options, of differing degrees of realism and sophistication, which can be used in the design/evaluation cycle." He gives examples beginning with a description of the form and functionality of the proposed product, from drawings on paper or screen to fully working prototypes. Stanton and Young (1999, apud Hall, 2001), in examining suitable ergonomics methods to improve product design, make a distinction between the types of prototypes according to the principal stages of the design process as follows:

1. Concept
2. Design
3. Analytical prototype
4. Structural prototype
5. Operational prototype

Here an analytical prototype corresponds, according to Hall (2001), to a computer-aided design and the structural prototype corresponds to a “hard-built" prototype. He states that the operational prototype refers to the design ready for commissioning. This is somewhat similar to Meister's (1990, apud Hall, 2001) design process, which refers to mock-up testing being performed during the planning, preliminary design and detailed design stages, and operational testing of prototype systems during the production and deployment stage.

There will not be a single design strategy that will suit all products, design contexts or budgets, as stated by Hall (2001). To achieve a good or usable design, the design process should be both user-centred and iterative, he adds. Nielsen and Mack (1994, apud Hall, 2001) have strongly argued for a combination of heuristic evaluation and user testing of prototypes; it is, however, extremely difficult to construct, let alone describe, a unified design strategy to cover all design situations. Therefore, Hall (2001) suggests that an appropriate design strategy based on user testing could be as follows:

1. Select the lowest level of fidelity deemed appropriate for the product being designed;

2. Select a small representative sample of target users as subjects (around five to seven);
3. Select representative tasks to perform (cf. ISO 1998);
4. Select appropriate usability criteria to measure-based on “problems" or formal ISO (1998) criteria;
5. Run user trials in a scientific manner-control for biases in test procedure, stress to the subject (user) that the product is being tested not them, and use think aloud technique with post-test interview of subject;
6. Redesign (based on problems found) with higher level of fidelity
7. Repeat process as necessary.

While this strategy has been based on user testing as the evaluation tool, heuristic evaluations may prove more cost-effective than user testing at certain appropriate stages or with certain types of prototypes. Further research may need to be done to determine when and under what circumstances heuristic evaluation and/or user testing are best suited. However, a human-computer interaction or usability expert, with a good understanding of the design “problem", should be able to provide appropriate guidance on evaluation during the design process (HALL, 2001).

To avoid usability problems, designers should employ an ergonomics or user-centred approach in their design work (NORMAN & DRAPER, 1986; NORMAN, 1988; SHNEIDERMAN, 1998; apud HALL, 2001). A user-centred approach involves knowing who the users will be, their capabilities, needs and expectations, their goals and the tasks required to achieve those goals, and the physical and social environments in which users have to achieve those goals. It involves processes of participatory design, user testing and iterative design (GOULD & LEWIS, 1985; SHACKEL, 1986; GOULD, 1995; apud HALL, 2001).

Participatory design implies involving users as participants in the design team while user testing involves users as subjects in the testing of design concepts or mock-ups from the very beginning of the design process. Iterative design implies a cycle of design, test and redesign, retest, etc (HALL, 2001). Gould and Lewis (1985, apud Hall, 2001) suggest that designers may believe ‘that iteration is just expensive fine tuning" but they argue that “with the current state of understanding about user interface design, it [iterative design] is the only way to ensure excellent systems". These general processes have been more or less formalized in International Standard 13407 (ISO, 1999), which also confirms the need to determine first the appropriate allocation of functions between user and technology.

However Eason (1992, apud Hall, 2001) describes three forms of user-centred design depending on the “type" of design being developed.

1. Generic, i.e. design for the user where the role of the user is as a subject in user testing of the design, e.g. consumer products or general software.
2. Bespoke, i.e. design by the user where the role of the user is as a participant in the design process, e.g. a software application for a company's specific needs.
3. Customizable, i.e. design adapted by the user where the role of the user is to control how the design interface looks and/or operates for them, e.g. individualizing the interface to personal computer operating systems.

Eason (1992, apud Hall, 2001) states that external experts may be needed to help identify the options but that users “own" the requirements. He also states that users will need help to evaluate whether a given option will meet the functional requirements as well as to assess its impact on usability and acceptability.

2.3 Types of prototypes

Prototypes can be generally classified into two categories: low-fidelity and high-fidelity. According to Rudd (1996), the fidelity level of a prototype is judged by how it appears to someone, and not by its similarity to the actual application. She also states that, in general, low-fidelity prototypes are quickly constructed, provide limited or no functionality and consequent limited interaction. This type of prototype is created to communicate, educate and inform and it is often used early in the design cycle to show general conceptual approaches without much investment in development. On the other hand, high-fidelity prototypes are fully interactive; they are not as quick and easy to create as low-fidelity prototypes, but faithfully represent the interface to be implemented in the product (RUDD; STERN; ISENSEE, 1996).

When time is a factor, it is still possible to develop an interactive, high-fidelity prototype of only a subset of the product's available function, which is called "vertical prototypes". In contrast, there is a so called "horizontal prototype" that contain high-level functionality, but do not contain the lower-level detail of the system; although they may be limited in scope, they can be quickly created to proved user interface interactivity that may be essential for specific product design decisions (RUDD; STERN; ISENSEE, 1996).

The following table summarizes the various advantages and disadvantages for conducting low and high-fidelity prototyping efforts.

Type	Advantages	Disadvantages
Low-Fidelity Prototype	Lower development cost. Evaluate multiple design concepts. Useful communication device. Address screen layout issues. Useful for identifying market requirements. Proof-of-concept.	Limited error checking. Poor detailed specification to code to. Facilitator-driven. Limited utility after requirements established. Limited usefulness for usability tests. Navigational and flow limitations.
High-Fidelity Prototype	Complete functionality. Fully interactive. User-driven. Clearly defines navigational scheme. Use for exploration and test. Look and feel of final product. Serves as a living specification. Marketing and sales tool.	More expensive to develop Time-consuming to create. Inefficient for proof-of-concept designs. Not effective for requirements gathering.

Figure 1 - Low vs. high-fidelity prototyping efforts (RUDD; STERN; ISENSEE, 1996)

2.4 Usability of electromedical devices

According to the standard 60601: 2012 ABNT p.16, an electromedical device is "an electrical device that has an applied part or which transfers energy to and from the patient or detects such transfer of energy to and from the patient and which is provided with no more than a connection to a particular power supply network and intended by its manufacturer for use in the patient diagnosis, treatment or monitoring as well as for the compensation of relief od the disease, injury or disability".

According to Mulqueen (2008), the Hospital and Dental Medical Equipment (EMHO) sector is a driving force for technological development, innovation inducer, as it demands intense intersection of several areas of knowledge, mainly Biomedical Sciences, Medical Physics, Computer Science and Engineering for Research, Development and Innovation. Mulqueen (2008) observed a worldwide high growth of the EMHO sector, which provides great financial stability to the industry even in a crisis environment. According to the Cooperation and Economic Development Organization - OECD (2000), the health sector has become one of the largest industries in the countries that integrate it with great dynamics in work creation and innovation.

Fiorentino et al. (2016) and Moreli et al. (2008) emphasize that the industries that compose the electromedical sector present a high innovation degree in scientific and technological knowledge, which gives them dynamism in the development and improvement of products and in competitiveness. The more technological the product is, the greater the added value it has and, therefore, the greater the profit obtained through its sale; this entails an economic progress for the country of origin of the company.

According to a report conducted by ReportLinker, an international marketing research firm, "Panorama of the Brazilian Health Market in 2020", with better living standards, health expenditures in the country are continually expanding, which is boosting the health sector. Health expenditures in the country are projected to grow at a CAGR of about 5,8 percent between 2016 and 2020. The main factors behind of the increase in health expenses include the prevalence of various diseases in the country, such as hypertension. Other major prevalent diseases addressed in the report include cancer, tuberculosis, obesity and diabetes.

According to the findings of the study, as future prospects of the Brazilian healthcare market and IT industry we are quite optimistic, since the technology segment witnessed significant mergers and acquisitions in 2015. As leading IT companies for whole health the world is also looking to Brazil as an ideal destination for an expansion of its business. Brazil has approved a new law allowing foreign companies to invest capital in private hospitals for the first time - an expected move to satisfy markets by capitalizing on a private health market with high demand and hiring for the much-needed industry sector. Investors from several countries are eager to inject resources without the Brazilian health sector.

According to the president of Abimed (Brazilian Association of High Technology Products Industry for Health), Carlos Goulart, the great domestic market has still not met demand in the area of Health, coupled with the increase in so-called chronic non-communicable diseases such as cancer, diabetes, hypertension and obesity, makes the Brazilian market even more interesting. "Brazil is undergoing a transitory situation of political and economic difficulties that influence the quotation of the dollar and decrease the collection, impacting the cost of health. However, despite this adverse scenario, the country has structural characteristics that make it potentially attractive and open up numerous investment opportunities in the health products sector", he says.

Agfa HealthCare, a Belgian company that provides diagnostic imaging and IT solutions worldwide, has been in Brazil for 20 years and realizes a broad market in the area of image scanning and systems integration in hospitals. "We see the country as a priority in strategic planning. In recent years, there has also been the acquisition of a Brazilian company to complement the portfolio of products available in the market, "says Agfa

HealthCare president for Latin America, Roberto Ferrarini.

The main specific usability standard for electromedical products is IEC 60601-1-6, 2004. It is a collateral standard, complementary to the IEC 60601 standard. It specifies an Usability Engineering Process for the manufacturer to analyze, specify, design, verify and validate usability when related to the basic security and the essential performance of the electromedical equipment.

The Usability Engineering Process, according to the standard, aims evaluation and mitigation of risk caused by usability issues associated, under normal utilization, with correct use and misuse; it may also be used to identify, instead of evaluate or mitigate risks, associated with abnormal utilization. The process is detailed by the international standard IEC 62366, which was created in 2007 to regulate usability engineering on medical products (ABNT, 2012a).

It was previously stated that errors are minimized and subjective user satisfaction is ensured through the use of prototyping, which also mitigates the expense of implementing the product under development. Prototyping therefore assists in the evaluation of the usability of the devices, proving to be fundamental for the optimization of time and effort employed in the project. For this goal, it is essential that the development of prototyping process is well planned so that usability problems can be detected and users' needs can be attended.

3 METHODOLOGY

In order to reach the objective of this work, a survey was carried out with companies listed in Hospitalar fair and based on the Forza (2002) methodology, following the phases listed below.

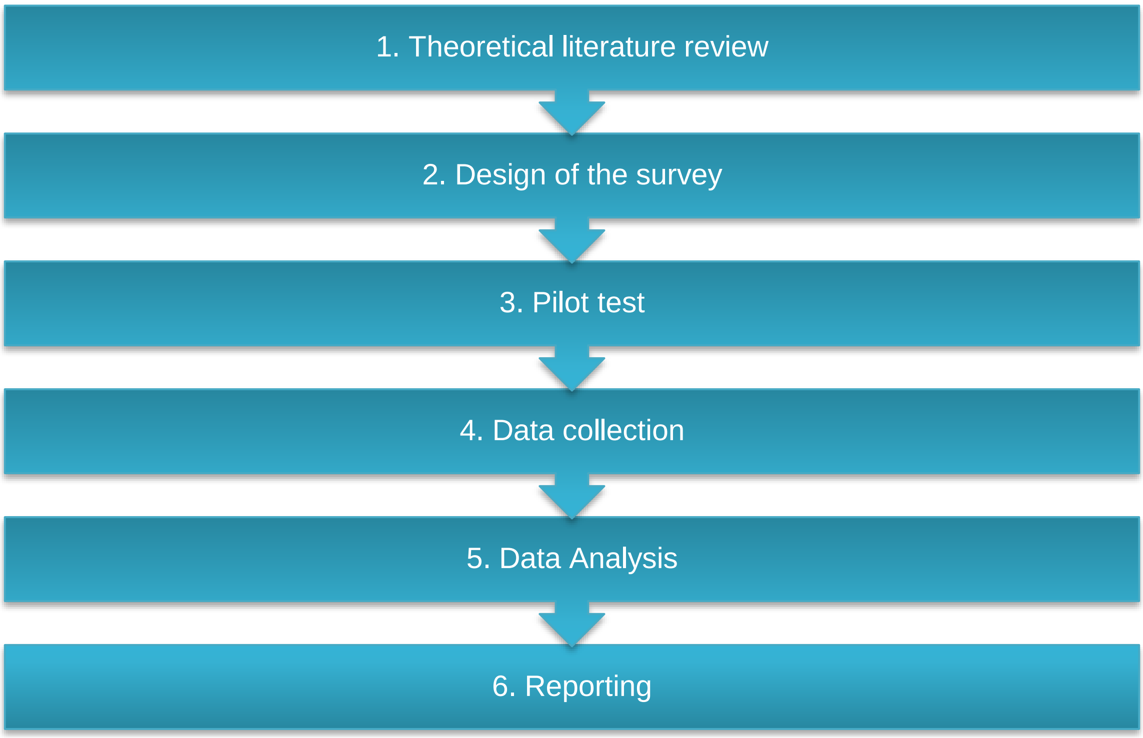

Figure 2 - Relationship between each stage of survey construction and application

Based on theoretical literature review, a table was built in order to present the main phases of the evolution of a prototype, from the lowest-fidelity to the highest-fidelity type, along with their main goals and purposes during each phase. It is important to emphasize that each phase represents the utilization of a specific type of prototype, that is, the development of one single product may include the implementation of different types of prototype, each one to be categorized as represented on figure 3. The categorization represented in figure 3 was essential to help brainstorming what parameters should be analyzed with the application of the survey, and consequently, what questions should be made to the companies that would be interviewed.

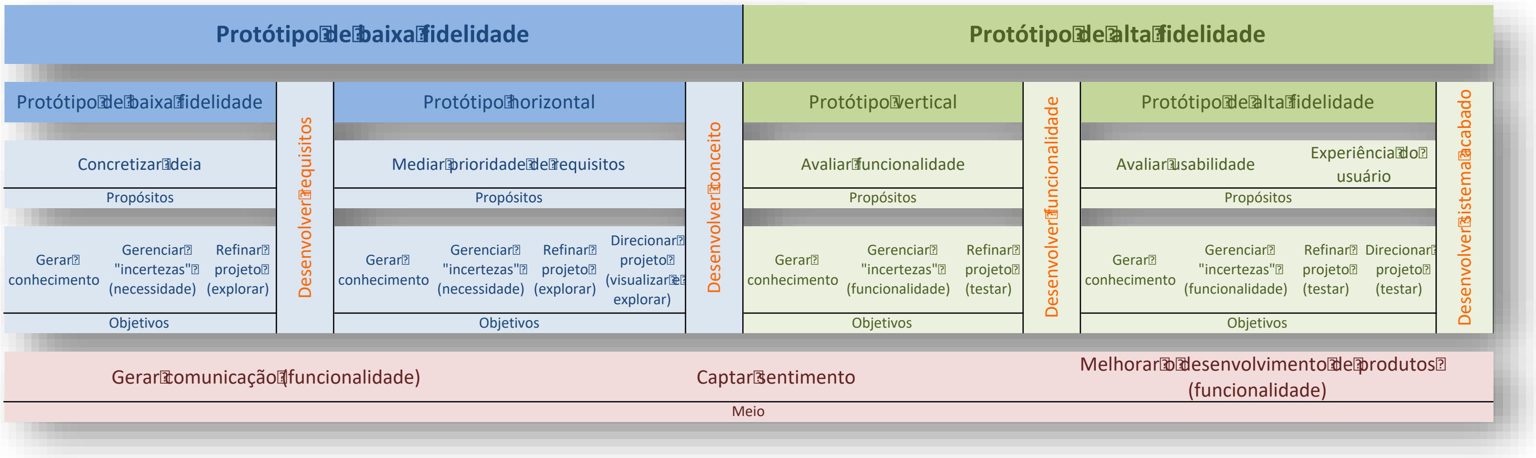

Figure 3 – Categorization of types of prototype

For the design of the survey, the main goal was to develop a questionnaire that would not take more than five minutes to be answered and that would not generate misinterpretation due to technical terms that might not be familiar to the industry. It was established that it would therefore contain only a few simple and objective questions, which would be easy to comprehend by the interviewees. The final questionnaire developed for the interview with companies of electromedical devices listed in Hospitalar fair is presented bellow:

1. What kind of prototype is yours?
2. What is the main goal of your prototype?
3. What kind of content would you like to measure with your prototype?
4. What are the purposes of your prototype?
5. What are the benefits of prototyping in the final product?
6. What are the challenges of prototyping in the final product?

After the elaboration of the questions to be inserted on the survey, a pilot test was conducted with three different persons, in order to evaluate the effectiveness of the content of the questions and whether there would be double or misinterpretation from expressions utilized. The average response time was around six minutes, what was not unacceptable but could be impoved, and some issues were identified by the pilot interviewees. These findings led to a few modifications in the questionnaire and resulted in the final one to be applied in the companies that would be surveyed, which was presented before this paragraph.

Once the survey was ready to be conducted, it was time to define the method to be utilized through data collection. Based on Forza (2002), it was applied a scoring scale, where 1 indicates maximum strength and 4 indicates minimum strength of the method under consideration. The method with maximum strengh (personal) was impracticable with all companies raised, so the first method chosen for conduction of the survey was by e-mail.

Factors influencing coverage and secure information	Mailed	Personal	Telephone	*E-survey*
Lowest relative cost	2	4	3	1
Highest response rate	4	1	2	3
Highest accuracy of information	2	1	4	3
Largest sampla coverage	1	4	3	2
Completeness, including sensitive materials	3	1	2	4
Overall reliability and validity	2	1	3	4
Times required to secure information	4	2	1	3
Ease of securiting information	1	4	3	2
Total	19	18	21	22

Figure 4 – Comparison of data collection methods (FORZA, 2002)

Telephone contact was made with each of the 62 companies raised, in each of which they redirected to the responsible sector. Explanation was made about the reason for that call by telling them about the project being developed by USP researchers, which had as one of its goals the improvement of the usability of electromedical devices. It was added that there was an attempting to help medical companies to become more competitive in the market through a better use of prototypes. It was then asked for the e-mail of the most appropriate professional, who would be a collaborator of a development area, an engineer or a project manager, to respond the survey.

The next step was sending an individual e-mail to each company, where I would introduce myself again and request the collaboration of the responsible individual to complete the survey, which would last approximately 4 minutes. A few weeks passed and the response rate was extremely low: only 10% (3 of 30) of the companies initially selected responded to the survey. The other 90% did not even open the email, which led us to a second attempt of application, this one through the telephone. The approach was the same as that contained in the email and, thus, the return was extremely higher than expected.

The survey was, therefore, applied by telephone and by this means, a relevant amount of answers was achieved, in which 34 other companies out of the 62 surveyed were interviewed. Among the 34 companies interviewed, two do not produce in Brazil and five do not have the habit of prototypes, since I could not get in touch with someone pertinent, what resulted in 27 successful responses over the telephone. The total of answers raised was therefore from 30 companies, all located in the state of São Paulo.

The companies that were successfully interviewed are the following:

- Astustec medical tecn. Com. E assist. Tecn. Em ap. Medicos ltda.
- Auto suture do brasil ltda
- Biocam
- Biotronik comercial médica ltda

- Bramsys indústria e comércio ltda
- Cardio Sistemas Comercial Industrial ltda
- Deltronix equipamentos ltda
- Dixtal biomédica indústria e comércio ltda
- Dräger indústria e comércio ltda
- Exxomed equipamentos ltda. - epp
- Fresenius Kabi Brasil ltda
- Global Tec Indústria E Com.De Prod.Médicos ltda
- Icelera Tecnologia em Equipamentos Médicos ltda
- Indumed com. Imp. E exp. De produtos médicos ltda
- J G Moriya repres. Imp. Exp. E comercial ltda
- Jamir Dagir Representações ltda
- Konex indústria e comércio ltda
- Ktk ind. Imp. Exp. E com. De equip. Hospitalares ltda
- Lifemed ind. De equip. E artigos medicos e hospitalares s/a
- Magnamed tecnologia médica s/a
- Medical cirúrgica ltda
- Meditron eletromedicina ltda
- Medpej - equipamentos médicos ltda - epp
- Multitone
- Panamedical sistemas ltda
- Rdi representações e distribuição industrial ltda
- Seca precisão para saude importação e exportação ltda
- Transmai - equipamentos médicos hospitalares ltda
- Xdent equipamentos odontológicos ltda - me
- Ventura biomédica ltda

The data analysis and reporting presented in the methodology are inserted in the results that will be discussed in the following topic of this work.

4 RESULTS

Prototyping can happen in an evolutionary way throughout the development of a product. To each evolutionary stage is assigned a different type of prototype; that is, the first type of prototype used may be a simple drawing on a sheet of paper. This, in turn, can evolve into a 3D drawing, from which a printed three-dimensional model can be obtained. A single prototyping process may therefore contain 1 or more types of prototypes. The types of prototypes are organized according to the material used (eg sheet of paper), the existence or not of representativeness of an interface (eg screen of a monitor) level of functionality, detailing and ease of modification. Each prototype has its own goals, purposes, benefits and challenges. All these parameters are taken into account in the following analysis of the answers obtained from the survey.

4.1 Types of prototype

Measuring customer satisfaction is a practice increasingly used in a number of industries, including healthcare and so on, and enables companies to identify which are the key factors that drive customers to be satisfied or dissatisfied. Knowing these reasons makes companies more successful in designing action plans to improve their customer experience. A survey was conducted to evaluate type, purposes, main goals, content measured, benefits and challenges associated to the utilization of prototyping with 30 medical companies in the state of São Paulo, Brazil. This section consolidates the results of this research and presents an insight into the factors that generate user's satisfaction.

The following clusters define, in a way, the different types of prototype according to their material, functionalities and other parameters, from the lowest fidelity to the highest fidelity ones:

1. Simple material, there is no representation of the interface, limited functions, not detailed, low easiness of modification;
2. Simple material, there is no representation of the interface, limited functions, detailed, low easiness of modification;
3. Simple material, there is representation of the interface, limited functions, very detailed, low easiness of modification;
4. Specific material, there is representation of the interface, complete functions, very detailed, low easiness of modification;
5. Specific material, there is faithful representation of the interface, complete functions, very detailed, low easiness of modification.

An analysis was made of the data collected from the survey and generated the following results about the type of prototype that is more often present on their product development: 53% of the companies interviewed utilize type 3, while 37% percent utilize type 4 and, finally, only 10% utilize type 5. It is possible to conclude that all the prototypes utilized from these companies are included in the category of more high-fidelity ones, what was already expected due to the complexity associated to electromedical devices as well as their development.

4.2 Purposes

Based on the types of prototypes specified above, the following question was made in order to point out the main purposes of the companies when utilizing prototypes:

- Materialize idea
- Mediate requirement priority
- Evaluate functionality
- Evaluate usability
- User experience

The questionnaire from the survey allowed the companies to mark more than one main purpose related to the utilization of prototyping. Despite the quantity of main purposes of prototyping for each company, it is important to emphasize that only one type of prototype is been analyzed for each company surveyed, which is the one that is more often used in their product development. Therefore, each line from table 1 represents the one purpose or more related to each of the 30 companies surveyed.

From table 1, it is explicit that all companies that responded the survey use prototyping to evaluate functionality and usability. On the other hand, only two companies uses prototype to materialize an idea, a purpose that is in fact mainly present in low-fidelity prototypes. Last but not least, the purposes referred to user experience mediate requirement are present in approximately 50% of prototypes analyzed, as the first one is one of 14 companies' prototypes purposes and the second one, one of 15 companies' from the 30 companies in total.

Type	Materialize idea	User experience	Mediate requirement	Evaluate functionality	Evaluate usability
3		x	x	x	x
3		x	x	x	x
3	x	x	x	x	x
3		x	x	x	x
3		x		x	x
3		x		x	x
3			x	x	x
3			x	x	x
3			x	x	x
3			x	x	x
3				x	x
3				x	x
3				x	x
3				x	x
3				x	x
3				x	x
4		x	x	x	x
4		x		x	x
4		x		x	x
4		x		x	x
4		x		x	x
4			x	x	x

Type	Materialize idea	User experience	Mediate requirement	Evaluate functionality	Evaluate usability
4			x	x	x
4			x	x	x
4				x	x
4				x	x
4				x	x
5	x	x	x	x	x
5		x	x	x	x
5		x	x	x	x

Table 1 - Type of prototype vs. purposes

As it can be observed, all of the companies surveyed have the evaluation of functionality and usability as one of their main purposes with the utilization of prototyping. In addition, only a few of them use prototyping to materialize an idea, which is typical for a low fidelity prototype; this is due to the fact that the object of study is electromedical device, which is a complex technological equipment that require specific material for prototyping and is categorized as a high fidelity type.

4.3 Main Goals

The next question intended to determine the following main goals of each company's prototype. This is essential to better understand the goals of the companies when utilizing prototypes and to help classifying, from low fidelity to high fidelity, the type of prototype that is being used.

- Generation of knowledge
- Management of uncertainties
- Refinement of project
- Conduction of project

As we can conclude from the survey data transcribed in table 2, companies that always generate knowledge as one of their prototype's main goals are more likely to also strongly manage uncertainties, refine project and conduct project. From all the 30 responses from the survey, we had the following results:

- Companies that always generate knowledge from their prototyping:
  - 55% has all the four goals previously described as their main ones, which are always present on their product development;
  - 11% also manages uncertainties;
  - 17% also refines project and the
  - 17% left of them manages uncertainties together with the refinement of the project.

- Companies that doesn't always generate knowledge from prototyping:
  - 50% always refines their project;
  - 25% manages uncertainties and refine their project; 8 per cent manages uncertainties together with a conduction of the project;
  - 8% refines and conducts its project and
  - 8% has none of the goals mentioned above as their main ones along with their prototyping.

Type	Generate knowledge	Manage uncertainties	Refine project	Conduct project
3	Frequently	Frequently	Always	Frequently
3	Frequently	Always	Always	Frequently
3	Always	Always	Always	Always
3	Always	Always	Frequently	Frequently
3	Always	Frequently	Always	Frequently
3	Frequently	Always	Frequently	Always
3	Always	Always	Always	Always
3	Always	Always	Always	Frequently
3	Always	Always	Always	Frequently
3	Always	Always	Always	Always
3	Always	Frequently	Always	Frequently
3	Frequently	Frequently	Always	Frequently
3	Frequently	Frequently	Always	Frequently
3	Frequently	Always	Always	Frequently
3	Always	Frequently	Always	Frequently
3	Frequently	Frequently	Always	Frequently
4	Always	Always	Always	Always
4	Always	Always	Always	Always
4	Frequently	Frequently	Always	Always
4	Frequently	Frequently	Always	Frequently
4	Always	Always	Frequently	Frequently
4	Always	Always	Always	Always
4	Always	Always	Always	Always
4	Always	Always	Always	Frequently
4	Frequently	Frequently	Always	Frequently
4	Frequently	Always	Always	Rarely
4	Always	Always	Always	Always
5	Always	Always	Always	Always
5	Frequently	Frequently	Frequently	Frequently
5	Always	Always	Always	Always

Table 2 - Type of prototype vs. main goals

4.4 Content Measured

Another parameter present on the questionnaire was the content measured along with the utilization of prototyping by the companies. The two contents analyzed were functionality, as technological complexity, and user interface, which is referred to the environment of machine-user interaction.

Therefore, another data about the companies that always generate knowledge along with the utilization of prototyping is that 72% measures only functionality, while 28% measures functionality and user interface. On the other hand, 42% of the companies that does not always generate knowledge as one of their main goals measures functionality, while 58% of them measures both functionality and user interface.

None of the surveyed companies utilize prototype with the intention to measure only user interface, but when this parameter is measured, it occurs together with the measurement of functionality. This may be observed from the table bellow, which shows the answers to the question from the survey about the content measured by the prototype used.

Type	Generate knowledge	Content measured
3	Frequently	Both
3	Frequently	Functionality
3	Always	Functionality
3	Always	Both
3	Always	Both
3	Frequently	Both
3	Always	Functionality
3	Always	Both
3	Always	Functionality
3	Always	Functionality
3	Always	Functionality
3	Frequently	Functionality
3	Frequently	Functionality
3	Frequently	Both
3	Always	Functionality
3	Frequently	Functionality
4	Always	Functionality
4	Always	Functionality
4	Frequently	Both
4	Frequently	Functionality
4	Always	Both
4	Always	Functionality
4	Always	Functionality
4	Always	Functionality
4	Frequently	Both

Type	Generate knowledge	Content measured
4	Frequently	Both
4	Always	Functionality
5	Always	Functionality
5	Frequently	Both
5	Always	Both

Table 3 - Type of prototype vs. content measured

4.5 Benefits of prototyping

The pros and cons consequent from the implementation of prototyping were analyzed as described in this topic and the following one. The benefits and challenges analyzed were chosen according to a study where was done an evaluation of the different types of prototype and the parameters related to the benefits and challenges due to prototyping utilization. This study was based on Rudd (1991) and Rudd (1996) and the parameters analyzed related to the benefits generated by prototyping were the following: decrease in total cost of the project, decrease in total duration of the project, rework avoided throughout the project and user satisfaction.

For each question about the possible benefits as a consequence of the utilization of prototyping, it was given a likert scale, used in order to obtain respondent's position about each item. For each question, it was given four possible answers scaled from "inexistent" to "very high/guaranteed". Some analysis were made in order to measure how strongly the benefits affect the project and if it is consequence of the selection of the type of prototype to be used.

By analyzing the table below, it can be inferred that 33% of the companies that include prototyping in their product development with the main purpose of generating knowledge presents only two of the benefits under discussion strongly evidenced, 56% presents 3 of the benefits and only 11% presents all of them. On the other hand, from all companies that does not always implement prototyping with the main purpose of generating knowledge, 25% of them produces only two of all the four benefits, while 58% produces 3 of the them and the 17% of the companies left produces all of them.

Type	Generate knowledge	Decrease in cost of project	Decrease in time scale of project	Avoid rework along project	User satisfaction
3	Frequently	Relatively low	Relatively high	Relatively high	Relatively high
3	Frequently	Relatively low	Relatively high	Relatively high	Very high / Guaranteed
3	Always	Inexistent	Relatively low	Very high / Guaranteed	Relatively high
3	Always	Relatively high	Relatively high	Very high / Guaranteed	Very high / Guaranteed
3	Always	Relatively low	Relatively high	Very high / Guaranteed	Relatively high
3	Frequently	Relatively high	Relatively high	Relatively high	Relatively high

Type	Generate knowledge	Decrease in cost of project	Decrease in time scale of project	Avoid rework along project	User satisfaction
3	Always	Relatively low	Relatively low	Relatively high	Relatively high
3	Always	Relatively low	Relatively low	Very high / Guaranteed	Relatively high
3	Always	Inexistent	Relatively low	Very high / Guaranteed	Relatively high
3	Always	Relatively low	Relatively high	Very high / Guaranteed	Relatively high
3	Always	Relatively high	Relatively low	Very high / Guaranteed	Relatively high
3	Frequently	Relatively high	Relatively low	Relatively high	Relatively high
3	Frequently	Relatively low	Relatively high	Relatively high	Relatively high
3	Frequently	Relatively low	Very high / Guaranteed	Very high / Guaranteed	Very high / Guaranteed
3	Always	Relatively high	Relatively high	Very high / Guaranteed	Very high / Guaranteed
3	Frequently	Relatively high	Relatively low	Very high / Guaranteed	Relatively high
4	Always	Relatively low	Very high / Guaranteed	Relatively high	Relatively high
4	Always	Relatively low	Relatively high	Relatively high	Very high / Guaranteed
4	Frequently	Relatively low	Relatively low	Relatively high	Relatively high
4	Frequently	Relatively high	Relatively high	Very high / Guaranteed	Very high / Guaranteed
4	Always	Relatively low	Relatively high	Very high / Guaranteed	Very high / Guaranteed
4	Always	Relatively low	Relatively high	Very high / Guaranteed	Relatively high
4	Always	Inexistent	Relatively low	Very high / Guaranteed	Very high / Guaranteed
4	Always	Relatively low	Relatively low	Very high / Guaranteed	Relatively high
4	Frequently	Relatively low	Relatively low	Very high / Guaranteed	Relatively high
4	Frequently	Relatively low	Relatively high	Very high / Guaranteed	Very high / Guaranteed
4	Always	Relatively low	Relatively high	Relatively high	Relatively high
5	Always	Relatively low	Relatively high	Relatively high	Relatively high
5	Frequently	Relatively low	Relatively low	Very high / Guaranteed	Relatively high
5	Always	Relatively low	Relatively high	Very high / Guaranteed	Very high / Guaranteed

Table 4 - Type of prototype vs. benefits

4.6 Challenges of prototyping

Analogously to the benefits analyzed, the parameters analyzed related to the challanges generated by prototyping were the following: cost of prototyping implementation, time of prototyping development, financial structure of the company for the prototyping development / implementation and finally the company's know-how for the prototyping development / implementation. It was also given a likert scale for each challenge analyzed from "inexistent" to "very high/guaranteed". These analysis were made in order to measure how strongly the challenges are present during the project and if it also is consequence of the selection of the type of prototype to be used.

By analyzing the table below, it can be inferred that 17% of the companies that include prototyping in their product development with the main purpose of generating knowledge have to strongly deal with all challenges under discussion, 33% have to strongly deal with 3 of them, 39% have to strongly deal with 2 of them and only 11% have to strongly deal with only one challenge from the ones analyzed. On the other hand, from all companies that does not always implement prototyping with the main purpose of generating knowledge, 17% have to strongly deal with all the four challenges, 58% have to strongly deal with 3 of them, 17% have to strongly deal with 2 of them and only 8% have to strongly deal with only one from all the four challenges under consideration.

Type	Generate knowledge	Implementation cost of prototype	Development time of prototype	Financial capital of company	Intellectual capital of company
3	Frequently	Relatively high	Relatively high	Relatively high	Relatively low
3	Frequently	Relatively high	Relatively low	Relatively high	Relatively high
3	Always	Relatively high	Relatively low	Relatively low	Relatively high
3	Always	Relatively low	Relatively low	Relatively high	Relatively high
3	Always	Relatively high	Relatively high	Relatively low	Very high
3	Frequently	Relatively low	Relatively low	Relatively high	Relatively high
3	Always	Relatively low	Relatively low	Relatively high	Relatively high
3	Always	Relatively high	Very high	Very high	Relatively high
3	Always	Relatively high	Relatively low	Relatively high	Relatively high
3	Always	Very high	Relatively high	Relatively low	Relatively low
3	Always	Relatively high	Relatively high	Relatively high	Relatively high
3	Frequently	Very high	Relatively high	Very high	Relatively low
3	Frequently	Relatively high	Relatively high	Relatively high	Relatively high
3	Frequently	Very high	Relatively low	Relatively high	Relatively high
3	Always	Relatively high	Relatively high	Relatively high	Relatively low
3	Frequently	Relatively high	Very high	Relatively high	Relatively high
4	Always	Relatively high	Relatively low	Relatively high	Very high
4	Always	Relatively high	Relatively high	Relatively low	Relatively low
4	Frequently	Relatively high	Relatively low	Relatively low	Relatively low
4	Frequently	Relatively high	Relatively low	Relatively high	Relatively high
4	Always	Relatively high	Relatively low	Relatively low	Relatively low
4	Always	Relatively high	Relatively low	Relatively high	Relatively low
4	Always	Relatively high	Very high	Relatively high	Relatively low
4	Always	Relatively high	Relatively low	Relatively low	Relatively high
4	Frequently	Relatively high	Relatively high	Relatively low	Relatively low
4	Frequently	Relatively high	Relatively high	Relatively low	Relatively high
4	Always	Relatively high	Relatively low	Relatively high	Relatively high
5	Always	Relatively high	Relatively low	Relatively low	Relatively low
5	Frequently	Relatively low	Relatively high	Very high	Very high
5	Always	Relatively high	Relatively high	Very high	Relatively high

Table 5 - Type of prototype vs. Challenges

5 CONCLUSION

It is possible to conclude that there is almost no user involvement in the process of prototype development and that, when it exists, it does not occur in an intense way as proposed and analyzed through literature review. This would guarantee greater satisfaction of the final consumer and would mitigate challenges such as costs of implementation, once rework would be avoided throughout prototyping. It may also be noticed that a large number of companies interviewed do not have the adequate financial structure or skilled labor for the development and implementation of the prototypes, as the great majority of them understand those internal factors as a major challenge.

What could also be inferred from the data analysis is that financial problems and lack of know-how are challanges so strongly present in prototyping since many professionals see the process as something that will only generate extra cost and time. That is, they do not have the perception of prototyping as something essential for a more efficient and accurate development of their products, as well as a process that will actually mitigate extra time and cost to the overall Product Development Process caused by lack of usability and other problems that may occur.

Due to the issues surveyed with the utilization of prototyping by the industry of electromedical devices, a couple of opportunities were identified in order to prevent companies from developing products that will fail, once, as stated by Crawford (2010), will (1) have no basic needs, (2) not meet their specified needs considering all disadvantages or (3) not properly communicate with the intended user. The first one is the intensification of user participation during all stages of the prototyping process, which would be essentially avoid rework and therefore decrease cost and time spent on the development of the product, as well as assure user satisfaction. The second opportunity identified regards to a more plausible allocation of resources by the companies for a better qualification of their collaborators, investing in specific teams to work with prototyping and therefore increase their labor skills.

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APPENDIX A - Questionnaire developed for the application of the survey with the electromedical companies listed in Hospitalar

Primary objective of the survey	Developments of the primary objective	Questions	Reference (Literature)
Evaluate how Brazilian companies of electromedicals devices use the good practices of the prototyping process during the product development process	Evaluation of the use of prototypes	- What kind of your prototype? - What is the main purpose of your prototype? - What kind of content would you like to measure with your prototype? - What are the purposes of your prototype?	Forza, 2002
	Benefits vs. challenges of prototyping	- What are the benefits of prototyping in the final product? - What are the challenges of prototyping in the final product?	Forza, 2002