Product design and development of novel technology-based products

Álvaro M. Sampaio (1,2), Ricardo Simoes (1,2) & António J. Pontes (1)

(1) Institute for Polymers and Composites IPC/I3N, University of Minho, Campus de Azurém, 4800-058 Guimarães, Portugal

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

msampaio@ipca.pt, rsimoes@ipca.pt, pontes@dep.uminho.pt

ABSTRACT: As products keep incorporating more technology, with a strong emphasis on microelectronics, it becomes obvious that improvements to traditional product design and development (PDD) processes are required.

Incorporating microelectronics in products, without the user being able to perceive them, while simultaneously ensuring their functionality, is not a trivial task. This is the case of RFID electronic traceability technology. The physical characteristics of RFID microelectronic devices, associated to the large variety of products and environments to which they are submitted, still limit the use of these technologies. In many cases, the microelectronic devices cannot simply be placed directly in the product. To solve that problem, the devices can be embedded in an add-on product that couples to the already existing product.

In this framework, we describe a case study of surgical instruments, in which the RFID tag cannot simply be embedded. We propose a methodology that to tackle this problem and we describe how it can be applied to design solution concepts. Prototype parts, that include an embedded RFID tag, were manufactured and are currently being subjected to usability tests. These tests will be a key factor for concept selection.

This work sets a first step towards a revised methodology for the design of the type of add-on products described, and opens the path for the optimization of product design and development processes to meet the needs of novel technology-based products.

1 GENERAL INSTRUCTIONS

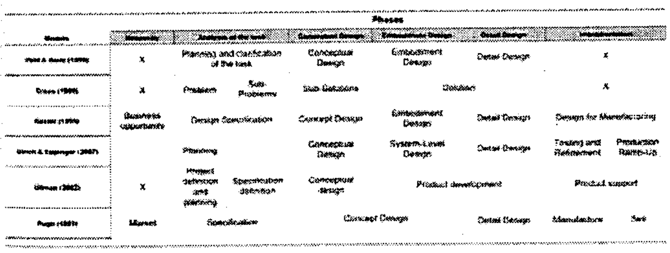
The microelectronic sector represents a global market of more than 6 trillion Euros, In the last 50 years microelectronics have invaded our daily life with a massive utilization in areas such as health, security and more. Virtually, it has invaded every aspect of human life, establishing a deeper connection with products based on new technologies.

Technology has always been an important element in the daily life of human beings, mainly in the attempt to master the world that surrounds him and in attaining its necessities in an efficient way. Although there is a dichotomy between the technological advances and the society in general, this is being modified by the mass production of industrial products. In industrial production, the inclusion of advanced technology has started to prevail in many products. All of these modifications in production had been supported by the necessity that the production industries had in differentiating products. In a competitive market products need to exhibit more features and functionalities in the attempt to obtain commercial success. In this way, novelty technology embedded in consumer products begins to be the major factor of differentiation. This phenomenon has its impact on the end user. In the attempt to implement the latest technologies in products, interaction principles change, and along time, change with higher cadence. Products shapes stop being the physical element of the interaction, and the way to use it shifts to a more abstract notion of use. During the mechanical era the interaction was concrete and, typically, quickly understood. The incorporation of microelectronic in products changes interaction in a drastic way. Push buttons and switches started, sometimes, to be replaced with a more intangible interaction (e.g. wireless). Therefore, user interaction becomes a central part of the development process, since users are becoming frustrated with the enormous number of features that the products have, and the common inability to identify them. A user-centered design approach starts to be needed in the development of technology-driven products. A development centered in the user, in an era in which the necessities are more imposed than real, will result in a more user-friendly product. In this microelectronics world, product design and development (PDD) processes need to be adapted and better organized. In most cases, this inclusion of microelectronics requires new manufacturing methods and new technical specifications for the product. One paradigmatic case is the need to incorporate microelectronics into already existing products. The difficulty/impossibility of simply embedding the microelectronic device into the product, maintaining the existing usability protocol, creates complex obstacles. For this case, a solution is to develop an add-on product that will be coupled to the original product or family of products. In this work we focus on this problem, specifically applied to families of existing products which require new functionalities through microelectronics.

2 REVIEW OF CURRENT PDD PROCESSES

Understanding the several design processes and their inherent methodologies is a key factor for managing PDD activities, aiding the development or improvement of products and the overall efficiency of companies. Thus, this section introduces a structure (Table 1) that enables establishing boundaries of the PDD and, simultaneously, presents an analysis of the common and distinct aspects of the overall phases of six different and widely employed design processes.

Table 1. Comparison of the PDD processes



Models	Phases							
	Necessity	Analyses of the task		Conceptual Design	Embodiment Design	Detail Design	Implementation	
Pahl & Beitz (1999)	x	Planning and clarification of the task		Conceptual Design	Embodiment Design	Detail Design	x	
Cross (1996)	x	Problem	Sub-Problems	Sub-Solutions	Solution		x	
Baxter (1995)	Business opportunity	Design Specification		Concept Design	Embodiment Design	Detail Design	Design for Manufacturing	
Ulrich & Eppinger (2007)		Planning		Conceptual Design	System-Level Design	Detail Design	Testing and Refinement	Production Ramp-Up
Ullman (2002)	x	Project definition and planning	Specification definition	Conceptual design	Product development		Product support	
Pugh (1991)	Market	Specification		Concept Design		Detail Design	Manufacture	Sell

This comparison focuses on prescriptive models, more framed by the engineering field, for the simple reason that it is in our interest to study not only the general models of PDD, but to analyze in more depth their activities and how these are performed.

The headings used in table 1 demonstrate the general agreement of design authors on common - often synonymously named - phases. Of the six phases, four are the phases commonly employed to describe the general PDD process: 'analyses of the task', 'conceptual design', 'embodiment design' and, 'detail design'. From the table one can see that different names are used for the same phase, some phases are divided in two sequential stages (Ullman, 2002), and some phases are grouped in just one (Pugh, 1991). Nevertheless, these four phases are actually the same in all processes, encompassing and aiming to achieve the same thing. Preceding these four phases is the 'necessity' phase, where the driver for the design is recognized. In the table, one can see that only half the listed processes consider the first phase (Pugh, 1991, Baxter, 1995, Ulrich & Eppinger, 2007). Thus, as the PDD process is driven by one or more of the following three factors (Belliveau et al. 2002), 'Technology', 'Market', 'Management', one can say that the 'Market' in these cases is the main driver in the analyzed processes, even though today's products continuously resort to a more intensive use of technology and are increasing their complexity by adding more features into each product (Simoes & Sampaio, 2008). As stated before, many of today's products are 'technology-pushed'. However, although it is not possible to observe directly from the table above, some of the processes (Ulrich & Eppinger, 2007, Pugh, 1991, Baxter, 1995) make reference and propose different approaches of the PDD process in the case of the 'technology' factor. In other words, they present an altered process when we are facing technology factors.

If this framework enables analyzing and comparing the general structure of the PDD processes, it does not tell the entire story, namely, 'what' and, more importantly, 'how' the overall processes are performed in each of the several phases. In order to establish a clearer understanding of the phases of each process we have dissected in detail the methods, techniques, and tools that characterize them.

It is very difficult to establish relations between PDD processes. On the one hand, they have been developed by different authors and for different process-targets, while on the other hand, they all tend to illustrate a process that, although with some specific aspects, could be equally implemented for several targets. From the analysis of the several methods and tools that each process features in its different phases, we can state that:

(i) the 'necessity' and the 'analysis of the task' phases are for collecting information and defining the task. Several methods can be implemented to achieve this, such as 'product segment maps', 'function analysis', or 'product-market-matrix'. One method that is common to all is the 'Quality function deployment' and all the phases end with a 'product plan' or a 'product design specification'. The differences pertain to the focus of the process itself, with some clearly concerned with the product (Pahl & Beitz, 1999, Cross, 1996, Ullman, 2002) performance and value, others with a focus on the product and the market (Pugh, 1991, Baxter, 1995), or even others encompassing all the previously stated aspects plus the management of the process itself (Ulrich & Eppinger, 2007);

(ii) the 'conceptual design' phase, although with different methods implemented, can be separated in two subsequent steps - analysis and synthesis. In the first step several methods are employed, such as 'problem decomposition', 'conjoint analysis' or 'customer selection matrix', are performed to achieve a higher understanding of the product. Afterward, all processes list several creative techniques such as 'brainstorming', 'gallery method' or 'morphological charts' with the purpose of designing some concepts for the product. The second stage reflects one common activity – the evaluation of the developed concepts. This evaluation takes place at the end of this phase, and is made by several distinctly named methods – 'evaluation criteria', 'concept evaluation', and 'concept screening/scoring matrix'. It can be said that, in general, they are identical, with minor differences in the focus, mainly pertaining to the precision of the methods and the number of subsequent steps,

(iii) the 'embodiment design' and 'detail design' are the phases with the highest differences among different authors. If, from a preliminary analysis, one can state that the general methods employed can be framed into the DFX strategies, a more detailed analysis highlights specific differences. For Ullman (2002), the phases are the same and are considered a 'product development' phase with the methods relying on 'concurrent design', several analysis, and DFX strategies. For Pahl & Beitz (1999), they are considered distinct phases; these authors present DFX strategies for the first phase but merely what they label as a finalization of the product with a document paper in the second phase. Cross (1996) discusses the importance of 'value engineering', and Baxter (1995) relies on the 'product feature permutation' and 'design integration'. Pugh (1991), as illustrated before, groups the 'conceptual design' and the 'embodiment design' phases, leaving the 'detail design' for 'functional cost analysis' and again for the 'method of controlled convergence'. One important point in Pugh's PDD is that it is established by a divergent (analysis) convergent (synthesis) activity along the overall process. Ulrich & Eppinger (2007) are the only authors that discuss the issue of 'product architecture' in detail and the 'assembly efficiency' of the product;

(iv) the last phase, 'implementation', is only defined in depth in two (Ulrich & Eppinger, 2007, Pugh, 1991) of the four PDD processes that consider that phase. The other two processes simply mention documentation for the manufacturing process.

3 RESEARCH AIM

When the PDD processes analysis described in this paper was started, the aim was on identifying the most promising process to be employed in products with embedded microtechnology. In that way, we hoped to decrease the gap between design research and design practice. By dissecting the different design processes and studying them in detail, we expected to lead to improvements in the effectiveness and efficiency of one of the processes. However, the conducted analysis clearly shows that these processes were conceived for development of new products. Whenever the analysis of existing products is discussed, it is in the framework of analyzing competitor products to establish or define product design specifications. In other words, none of the studied processes are optimized for the development of products that need to perform their function coupled with other already existing products.

This type of PDD process unquestionably requires a detailed analysis of the shape, size, and other physical and functional characteristics of the existing products. Only in this way it becomes possible to develop a product with embedded microelectronics to be coupled to several different products. Another gap in the analyzed processes is the absence of users in the overall process. Although some of the processes suggest that users can be consulted during the process (Ulrich & Eppinger, 2007, Pugh, 1991), this is merely in the first phases with the intention of understanding market needs.

4 RESEARCH METHODOLOGY

The methodology adopted, which can be seen in fig. 1, only encompasses the first three phases of the PDD process – Necessity, Analysis of the task, Concept Design (From table 1). The final output of this part of the PDD process is the definition of a concept design. Subsequent work will expand the study to the other phases of the PDD process.

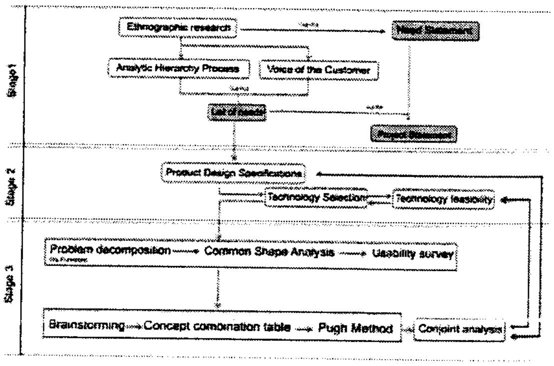


Fig. 1. Flow diagram of the PDD process implemented.

As stated, PDD is normally driven by 'Technology', 'Market' or 'Management' factors. These are different needs for developing a new product, so we can say that in the beginning of each product development process there is always a problem to face. It has been widely recognized that problems are ill-defined (Rittel & Webber, 1984), because they are not completely determined. This is why a project statement always needs to be fully developed. To develop the project statement, in our view, three methods need to be implemented. These methods exhibit two outputs: list of needs and need statement, which together constitute the problem statement.

In this initial Stage the methods are, Ethnographic Research, Analytic Hierarchy Process, and Voice of the Customer. Ethnography, in general terms, is the description of a social group based on the observation of their behavior in their natural environment. As stated in PDD processes, problems and their full understanding is a difficult task, but an imperative for success. As such, ethnographic research is a powerful method, as it enables defining and understanding the users, how they interact, what they desire, as well as their perceptions and behaviors. Through this method, it is possible to identify needs that were hidden and to realize the impact of a product in a specific context of use. This method combined with the Analytic Hierarchy Process, allows understanding the weight that every identified user has on the PDD process. As different users can use the same product for distinct proposes and in different ways, the last method – Voice of the Customer – allows identifying what the users really want from the product.

The second Stage in this PDD process is to develop the Product Design Specifications (PDS) and to select and evaluate the technology that is going to be employed. As stated by Pugh (1991), the constituent elements of a PDS are applicable to all products, independently of the technology used. That is why selection and validation of the technology is listed afterwards.

Finally, Stage 3 has its focus on the evaluation of the existing products and the way that users perceive them. This combination of methods establishes information on the shapes that will be the basis for coupling the add-on product, but at the same time the understanding of existing usability protocols that users consider immutable. It is also where creative techniques and the evaluation of concepts are achieved. These later methods are all dependent on the user participation. However, we can clearly state that all the methods used in this process need to have direct or indirect participation of the end user, and the optimum use of that participation can have a huge impact on the success of the design process.

5 RESEARCH CASE STUDY

5.1 *Stage 1*

When producing medical devices, manufacturers must design them to fit the 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. It is even more important to track the product inside the health provider's facilities, during use, cleaning and sterilizing. As such, we have selected as a case-study the issue of coupling a microelectronic device to surgical instruments in order to track them.

Despite first appearances, this is not a trivial task, as there are many challenges in the incorporation of a microelectronic device in surgical instruments, including: the environmental conditions, as the device needs to perform in high humidity, contact with metal surfaces, need to withstand extreme temperatures, and other factors. Also, it must be insured that the placement of the microelectronic device poses absolutely no threat to the patient, nor hampers or limits the performance of the health professional using the surgical instrument. Although the major improvement in coupling a microelectronic device will be seen in the performance of the scrubbing nurse and on the sterilization technician, surgeons' procedures and requirements are the most critical issue. Therefore, one of our goals is the development of a product that features an embedded microelectronic device, and can be physically coupled to surgical instruments, with no impact on its usability. The major task is to develop this product in a way that allows it to be coupled to a large number of existing surgical instruments; at the very least, all instruments contained in a generic set such as that shown in Fig. 2.

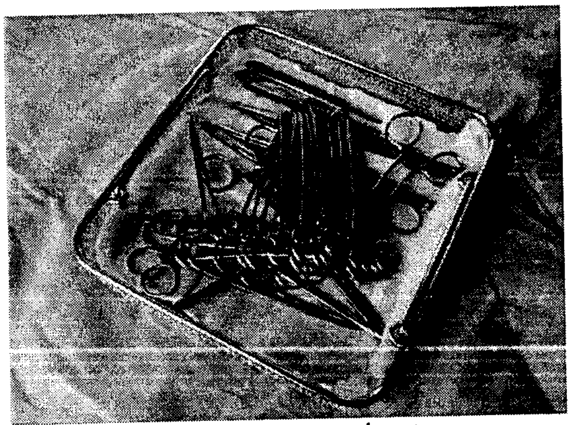


Fig. 2. Surgical instruments generic set.

A surgical generic set is composed by two needle holders, twelve hemostatic forceps, three scissors, two dressing forceps, two tissue forceps, two scalpel handles, a Backhaus towel forceps and a McGivney forceps, in a total of twenty five instruments.

The inclusion of the tracking device will allow for a fast and accurate count during surgical and sterilizing operations, and, at the same time, the knowledge of the number of uses that a specific instrument has had, as well as the specific set to which it belongs (since several sets can be used in just one surgery and typically end up mixed together). This 'system' will prevent several typical errors, such as miscounting, misplacement, theft, and accidental disposal of instruments, as well as allowing for full traceability of the instruments. This product will allow automated, none-line-of-sight inventory, meeting the requirements of the surgical environments and the needs for product traceability.

5.2 *Stage 2*

One of the technologies being considered by many industries to face the problems of traceability is Radio Frequency Identification (RFID). This technology involves electronic antennas that emit radio signals and devices called readers that process the signal returned by the RFID tags. 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 revolutionize 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. As stated in stage 1, several high level specifications need to be evaluated. In this case, technical feasibility of the selected technology was assessed. We started by selecting the smaller RFID available in the market (glass ampoule tag) with approximately 12mm length x 2mm diameter with 64 bits capacity, and attempted to injection mold the device into a polymeric test specimen (Fig. 3) to see if the RFID was damaged by the high temperature and pressure, and to validate that the position of the RFID did not change with the flow of the polymeric material during the injection process.

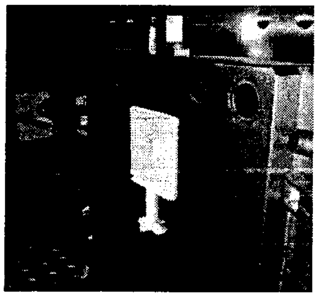


Fig. 3. Injection molding of an RFID tag in a test specimen.

5.3 *Stage 3*

This stage is of paramount importance, since placing a novel feature in surgical instruments (such as an externally coupled product) needs to be very carefully considered. Surgical proceedings cannot be modified easily, nor can these modifications to the surgical instruments hamper the way surgeons handle them. Thus, for the shape analysis previously discussed, a 3D scanner was employed to obtain models for each component in a generic set of surgical instruments. The 3D models of the surgical instruments were studied with a software in order to identify common zones in the different instruments (see Fig. 4).

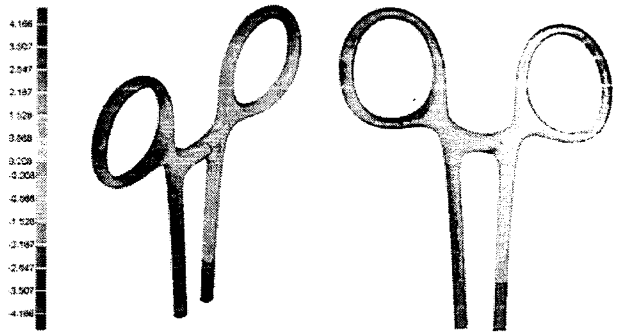


Fig. 4. Common shape analysis of the needle holders with the hemostatic forceps.

Simultaneously, inquiries were made with practitioners (medical doctors) in order to establish which areas of the instruments are candidates for coupling an external component, without impact on the surgical procedures. Doctors were requested to mark in pictures of the instruments which areas must not be affected in any way, either due to becoming in direct contact with the patient or being used by surgeons to handle the surgical instruments (an issue made even more complex by the fact that different practitioners hold and use the same instrument in a different way). A typical example of this study is shown in Fig. 5.

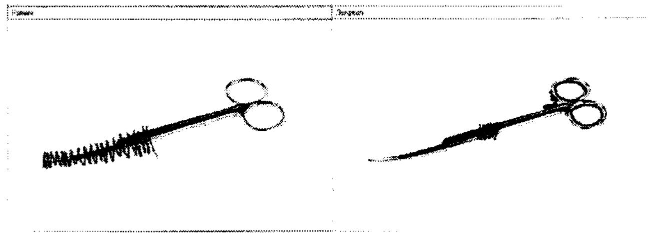


Fig. 5. Identification of zones with different functions in a surgical scissors.

Using this approach, with the combination of shape analysis through 3D software and the survey conducted on several independent medical doctors (surgeons), it was possible to establish likely zones for coupling the RFID-enabled external product to the instruments (Fig. 6).

In that figure, the shade of green indicates how adequate the zone is for coupling the RFID-enabled product. Clearly, it shows how the best location would be the base of the finger loops. Note that for perspicuity sake, color shading was only applied to one half of the instrument, since it is symmetrical. Obviously, the results apply to both finger loops of the instrument.

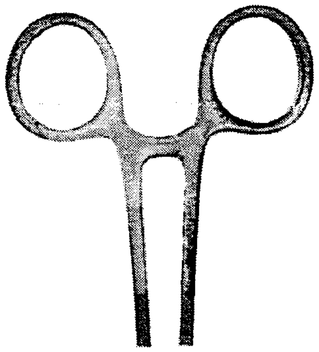


Fig. 6. Result of the possible zones for coupling the RFID (shown for a hemostatic forceps).

A major aspect in obtaining successful product development is the involvement of users throughout the PDD process. This is clearly the case of surgical instruments. Operating rooms are places where unforeseen circumstances need to be controlled so that mistakes are minimized (ideally, prevented). Thus, after identifying the possible zones to couple the external RFID-enabled device, it was necessary to develop the first concepts, with a strong involvement of final users. To this purpose, a brainstorming session was conducted, which included the participation of surgery specialists. In the brainstorming, surgeons, nurses, sterilization technicians, and designers have produced several concepts and discussed them in order to match the requirements listed in Stage 1 and the selection of the technology in Stage 2. From the several concepts that resulted from brainstorming, two were selected for development (Fig. 7).

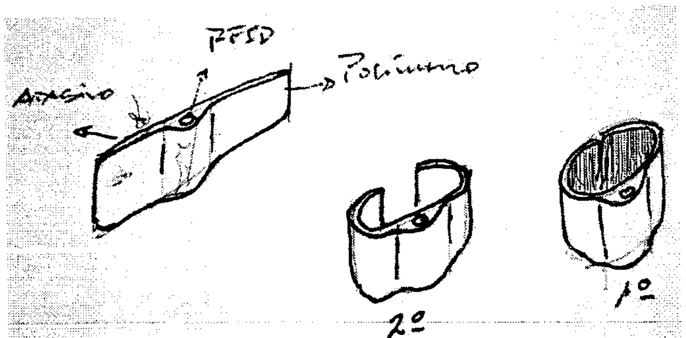


Fig. 7. Two concepts selected from the brainstorming results.

From the analysis of the selected concepts, new insights emerged about our understanding of the problem, which require a revision of the technology selection and technical feasibility. This is mainly due to the means to attach the RFID-enabled product to the surgical instrument. In other words, the design of the product and the likely zones for coupling seem to be identified and validated with the users (surgeons), but the technology to perform the assembly of the add-on product still needs to be better explored and only then can the final validation with prototypes be performed by users.

6 CONCLUSIONS

The most widely employed PDD processes have suffered little to no changes in recent decades. Thus, they are not optimized for some characteristics of current technology-driven products. This is particularly the case of embedded microelectronics. It is possible to identify minor changes to traditional PDD processes to increase efficiency and improve the success odds of the developed product.

In this work, we analyze multiple PDD processes and propose the first stages of a PDD process, up to concept generation, aimed at products with embedded microelectronics. We then describe its application to a specific case-study, namely the incorporation of RFID tags into surgical instruments. Nearly all the employed methods involve the final users in the process, in a user-centered approach, a vital aspect of PDD.

Ongoing work includes the preparation of functional prototypes for field tests by surgeons, which will enable concept selection and the subsequent stages of detail design. Subsequently, we shall extend this work to the other phases of the studied PDD processes.

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REFERENCES

Baxter, M. 1995. Product design: a practical guide to systematic methods of new product development, Chapman & Hall, New York.

Belliveau, P. Griffin, A. Somermeyer, S. 2002. The PDMA toolbook for new product development, Wiley, New York.

Cross, N. 1996. Engineering design methods, (2nd. Ed.). Wiley.

Pahl, G. & Beitz, W. 1999. Engineering Design: A Systematic Approach, (2nd. Ed.). London, Springer

Pugh, S. 1991. Total Design. Integrated methods for successful product engineering, Addison-Wesley Pub. Co.

Rittel, J. & Webber, M. 1984. Planning problems are wicked problems, In N. Cross (Ed.), Developments in Design Methodology, Wiley, pp. 135-144

Simoes, R. & Sampaio, A. M. 2008. "Effect of technology-driven products in the future of product design and development," Proceedings RPD 2008 Designing the Industry of the future, Oliveira de Azeméis, Paper 8048.

Ullman, D. 2002. The mechanical design process, McGraw-Hill, New York.

Ulrich, K. & Eppinger, S. 2007. Product Design and Development. McGraw-H