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ERGONOMIC-FOCUSED PRODUCT MANAGEMENT OF BLOOD GROUP SEROLOGICAL PRODUCTS

Doctoral theses

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Budapest, 2015
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I. INTRODUCTION

In my dissertation the focus is on the development of a medical device (product line) performing blood group serological tests. Transfusion serves as a solution for the substitution of blood what is vital for the human body. Blood group serological tests ensure that everyone gets appropriate blood products. Mistakes are unacceptable (since a false negative result may result in death). Blood products have to go through a long process in order to be appropriate for the patients (meaning the antigens of transfused red blood cells match those of the patient's red blood cells). In this process the key elements are the blood analyzing human resource and the medical devices they use. Thus, the development of such medical devices is of high importance; that is why my doctoral research aims at it.

My doctoral thesis is an example for the relationship between technical sciences, medicine, the user friendly (ergonomic) product development and social sciences, when psychologists, engineers, and managers work together. The synergy based on the coherent parts – just as in case of the focus groups – gave us more than expected.

It is important to know that the characteristic of user-friendliness cannot be considered as a separate matter; and it cannot be attached to the product subsequently. A product is usable if the whole product development process is imbued with user-friendliness preferably through as many phases of its life cycle as possible.

II. AIM OF AND PRELIMINARY INFORMATION ON THE RESEARCH

In my thesis I focus on a 7-year-long product development process. When choosing a company and product line, it was important for me that the know-how should be 100%-ly Hungarian (e.g. regarding the patents). The tender mentioned below met my expectations, so I had the opportunity to deal with a blood group serological product line produced in Hungary. As a main method I continuously detect and analyze the occurring problems of the users, and I contribute to the constructional solution for them. To be able to do so, I organized and conducted a longitudinal research among others: I collected user requirements of more than 200 employees of more than 70 Hungarian medical institutions within the frame of focus group analyses in 2008, 2010 and 2012.

Relatively serious knowledge on the fields of medicine, biochemistry, chemical engineering, construction, robotics and informatics are needed to be able to write my thesis. I needed to acquire that complementary scientific and technological knowledge in order to develop my thesis, for what the project realized within the frames of the Jedlik Ányos Program (won by the
Department of Ergonomics and Psychology (BME) and Cytotech Instruments Ltd. was a good opportunity, since I worked at the manufacturer for a longer time as a trainee. The ergonomic focus of the topic requires the acquirement and implementation of ergonomic analyzing and evaluating methods on a more advanced level on quite different subfields, such as hardware ergonomics, optimization of mental effort, software ergonomics, which all appear in my thesis.

AIM
In my thesis I analyze development goals which are determined by medical aspects, regulated by law, and modulated by user needs. By means of the primary, secondary empirical research and the studying of the literature, I intend to come to conclusions by means of which I hope to understand more deeply the developer’s, (end)users’ and medical institutions’ point of view, the product functions and the specific interactions of those different factors (Figure 1). I believe that by means of a deeper understanding, useful guidelines can be made up for those taking part in another medical development process.

![Figure 1: The relation of the goals of the development](image)

In case of medical devices the users’ viewpoints are considered in different ways and to different extent. On the one hand the laboratory employees have little voice in procurement matters directly. On the other hand as they work with those devices on a daily basis and they have first-hand experience on which of them can be used the most effectively and safely (under the most convenient circumstances), therefore their supervisors consult them on their opinion, and so their needs can reach upper levels of the hierarchy, after all, in an indirect way.
SUB-TARGETS
The complexity of the subject offers the opportunity to define sub-targets as well.

1) In my doctoral thesis I touch upon the involvement of the users within the process of product development: benefits, difficulties and the adaptable models are presented based on the literature.

2) Subsequently, the application and the experience earned from that is presented through a specific example of product development.

3) As an outcome of the dissertation, I would like to evaluate and present the important and useful experience drawn from the abovementioned for developers and manufacturers. Viewpoints and topics will be presented (e.g. standards, legal acts, guidelines, innovation, dual-drive model concept, participative development) that provide the manufacturers of medical equipment with practical support in their future product development processes. The companies in scope can use these blocks as a starting point when creating their new products or improving their development processes.

The theoretical background of the dissertation can be divided into units of based on the complexity of the given topic. The theoretical overview (similarly to the structure of my hypothesis) starts with a broader review and focuses more and more specifically to the subject of the dissertation. The complexity of the subject and the holistic analyses of the multi-disciplinary research require the specification of all the topics detailed below. I intend to merge all those units into one comprehensive theory, putting special emphasis on highlighting the synergies explicitly as well.

The dissertation itself is interdisciplinary, hence it details different topics. Setting a limit to the depth and elaboration of the topics is inevitable. However, my intention was to identify the key elements in each topic that are fundamental to mention and cannot be ignored. The driving objective – among others – is to provide the medical equipment manufacturers and distributors (especially in the field of blood type serology) with a practical approach and best practices. Some of the chapters (e.g. the economic review) are just a snapshot, however many topics (e.g. innovation models, ergonomics, usability) are presented that may contribute to the improvement of the product development process, eventually leading to increased competitiveness of the company. All those can obviously be just a part of the ultimate success.

The following greater unit (second chapter) presents the marketing aspects based on the literature that serve as a theoretical background. Within the framework of that, innovation theory, different
(technology, market, dual-driven) product innovation models and the open innovation paradigm is presented. That chapter is closed with the definition of quality from a marketing and quality management perspective.

The following greater unit of the theoretical background presents product innovation, ergonomics and user involvement. That chapter includes economic related sub-chapters (e.g. product development inputs) and an example of a company. Among others, ergonomic requirements of blood group serological devices (determined by medical professionals or standards) are presented. User involvement and the possibility and necessity of the participative product development are also demonstrated.

The third chapter starts with the economic outlook of the market of the medical device industry: a parallel is drawn with the word economic situation, focusing on Western and Central Europe. It is important to present the different markets, since the medical device analyzed in the dissertation is in competition on the global market, and its competitors represent themselves in Hungary, too. After that the macro environment is indicated, for what the frame is the STEEP analysis. The presentation of blood group serology (the most important concepts, applied methods, techniques) and the market of the blood group serological device industry follow. As a final part of the chapter, the ACT\(^1\) product line that is in the focus of the dissertation is presented: users are specified; its strengths and weaknesses are shown (in the reflection of its competitors). The chapter is ended with a more practical part: I present the SWOT analysis of the ACTs.

The chapter presents the empirical research about the longitudinal analysis that is examined within my dissertation. First I present the theoretical background of the research methodology (focus group analysis), then the previously completed research of the subject is demonstrated. Thereafter, the aim of my research and the sample are presented. The methodology of the processing is introduced separately, since the applied content analysis and the statistical testing may not be that conventional. The most important part of the chapter is the review and analysis of the five hypotheses.

After presenting the results of the empirical research, my research activity is summarized, and my new scientific outcomes are shown. Finally, the directions for further research are reviewed.

\(^1\) ACT is the abbreviation for Automatic Coombs Test Analyzer.
III. MAIN RESEARCH RESULTS

By presenting and analyzing in detail the product development process based on involving users in my dissertation, my aim was to provide medical instrument manufacturers with information that can be used for their future product development projects in practice as well. On the basis of those, I have formulated the hypothesis detailed in the followings. The hypothesis focus more and more specifically on the given product line analyzed in the dissertation.

As it can be seen in the following figure, I used the transcripts of the conducted focus groups to analyze my hypotheses. Firstly, I used ATLAS.ti 6.1.1 content analyzer software to process the transcripts of the focus groups. After that, I analyzed Hypothesis II. and IV. by means of descriptive statistics; and I used IBM SPSS (Statistical Package for the Social Sciences) Statistics 23 software to do the statistical analysis of Hypothesis I., III. and V.

**Hypothesis I.** The requirements of different groups of users (assistants, executive assistants, analysts, heads of laboratories, lead physicians) regarding the very same medical device differ (in some cases they are controversial, in other cases they complete each other) due to their dissimilar duties. On one hand, those differences can be well interpreted; on the other hand they can serve as the basis for product development decisions.

In case of medical instruments the group of users and customers typically differ, which indicates different requirements imposed on the products. Regarding blood group serological devices, which
serve as the basis of the dissertation, it can also be said that even the group of users can be divided into two: assistants use the devices with different frequencies than e.g. heads of laboratories or lead physicians, and their scope of responsibility differs, too. Thus, it may lead to different requirements imposed by the two user groups that may nuance the product development aspects and may contribute to product development by useful pieces of information.

When analyzing my **first hypothesis**, at first I used 43 evaluation criteria by means of which I intended to compare to what extent the needs of the assistants and those of the physicians differ regarding the same medical device. After the data cleaning needed for running the chi square test, I examined the differences between the two user groups by means of 30 criteria. Since there were I ignored 4 criteria which were not mentioned by any of the user groups. In case of approximately half of the remained 26 criteria (i.e. 12) significant or remarkable differences were found between the ration of the mentioned evaluation criteria made by the assistants and physicians; while in case of 13 criteria the difference was only minor. In case of one criterion, equality was found between the numbers of the mentioned opinions. The result of the chi square test is significant (p<0,05) which **globally confirms my hypothesis**. However, the 12 vs. 13 criteria cannot be considered as vast majority. Although the number of the remarks is rather indicative, I consider **H1 only partly confirmed**. During the examinations, only two groups (assistants and the physicians, who are higher in the hierarchy and are responsible for the final validation) were differentiated, so finer differences (e.g. between the point of view of the biologists and heads of laboratories) could not be detected. That is also in favor of the **partly** confirmation.

**Thesis I.: The requirements of two groups of users (namely the group of assistants, executive assistants and that of the analysts, lead physicians) regarding the very same medical device differ from a lot of aspects (in some cases they are controversial, in other cases they complete each other) due to their dissimilar duties. On one hand, those differences can be well interpreted; on the other hand they can serve as the basis for product development decisions. (A)**

* The letters (within brackets) refer to my publications related to the given thesis (see Chapter V.)

The article (A) relating to Thesis I. presents all the three phases of the research, and the results got as well. It also details the participants of the focus groups, thus, the groups of users indicated in the hypothesis.
Related to the theses, it may be novel that earlier a longitudinal research as comprehensive as presented in this dissertation and involving so many medical professionals has not been carried out in case of the development of a specific product line. Based on the above, the need assessment is quite inclusive.

**Hypothesis II.** Quantitative hypothesis analysis can be carried out by means of data gained from focus groups conducted properly and content analysis involved. Furthermore, that approach can contribute to a better detection of hidden (implicit) user needs.

Although involving users in the product development process might not be recent, assessing the users’ needs through unconventional methodologies in case of medical devices is rather in its early stage in Hungary. User satisfaction monitoring (usually done by means of surveys or telephone calls) are usually carried out, but methodologies more complex than those are rarely conducted or at least fewer cases are published. In my dissertation, such a methodology, namely the focus group analyses is presented, placing special emphases on the user needs that can be detected by means of it. Some of the data gained through focus group analyses were computed by mans of text analytics. On the one hand it allows a quantitative analysis of the hypotheses: I used a text analytics software to evaluate the first, third and fifth hypotheses. The confirmation of the three hypotheses in question reflects back on the first hypothesis. On the other hand I also intend to analyze the possible identification of the hidden (implicit) user needs within the frame of the first hypothesis.

On the one hand, the **second hypothesis** has a methodological viewpoint: I tested whether focus group analysis supported by text analytics can appropriately be used to examine hypotheses quantitatively. I tested the first, third and fifth hypotheses (in case of which I used text analytics) to be able to prove H2. As it can be seen in this chapter, the hypotheses in question are confirmed, which leads to the confirmation of the second hypothesis.

On the other hand, I also examined what kind of user need can be detected by means of involving text analytics within the second hypothesis. It needed a more analytic deepening in the transcripts. I examined the occurrence of implicit needs (besides explicit demands) especially through examples gained from the focus groups, by involving text analytics. I came to the conclusion that many implicit needs could have been detected even though a special attention had not been paid to them during the research; thus, **H2 is confirmed**. Users typically identify product
features at first (e.g. the need for a stronger holder for reagents), but later on, when asking for more details, deeper insights, motivation and values can be detected. The following hypothesis was formed in accordance with the abovementioned.

Thesis II.: Quantitative hypothesis analysis can be carried out by means of data gained from focus groups conducted properly and content analysis involved. Furthermore, that approach can contribute to a better detection of hidden (implicit) user needs. (C*, E, F, G, I)

* The articles related to the second hypothesis tell about self-evaluation in detail; and the usual methodologies used for detecting user needs (e.g. surveys) are also mentioned. Related to the theses, it may be novel/innovative that since focus group analysis is a relatively less-used approach for collecting user needs in Hungary (especially in the medical equipment industry); by means of the dissertation that methodology can be understood more. It is also shown how fine (implicit) user needs can be detected by means of focus group analyses. Although the research did not consciously focus on analyzing the dialogues that deeply, including them intentionally could be considered.

Hypothesis III.: Involving the users in the product development process of a blood group serological product line based on a systematic and adequate methodology, leads to an increasing ergonomic quality of products in terms of safety, efficiency and comfort.

A longitudinal research can serve as an exceptional opportunity for analyzing user needs related to the continuous improvement of an exact product from different aspects and to different extent. I analyze user needs related to safety, efficiency and comfort (more restrictively to ergonomics) that were collected during the focus groups conducted in 2008, 2010 and 2012. The continuous innovation of one concrete product line was in the center of the focus groups mentioned. However, I further developed a product innovation model (based on the model of Roozenburg and Eekels (1995)) that can be adapted to the development of other products than medical devices as well.

During my third hypothesis, I examined by means of longitudinal data whether the involvement of users in the product development process and integrating their needs into it could lead to
higher and higher ergonomic quality of a product line. Ergonomic needs collected on the focus group analyses conducted in 2008, 2010 and 2012 are studied along criteria related to safety, efficiency and comfort. I examined whether integrating the user needs to the product development process leads to mentioning less ergonomic problems. I used One-Way ANOVA to compare the three phases. Comparing the transcripts of the focus groups conducted in 2008 and 2010 did not lead to significant results. However, the results gained from comparing the transcripts of the focus groups conducted in 2010 and 2012 were significant. At the same time, it was found that in the long term (comparing the results gained in 2008 and 2012) a significant decrease can be seen. The decreasing tendency was appointed by means of the “means plot” and group averages, so the hypothesis is confirmed.

The following hypothesis was formed in accordance with the abovementioned.

**Thesis III.** *Involving the users in the product development process of a blood group serological product line based on a systematic and adequate methodology, leads to an increasing ergonomic quality of products in terms of safety, efficiency and comfort in the long run. (H*, J, K, L, M, N)*

Efficient use of energy and neutralizing environmentally harmful materials are mentioned among others in the chapter related to the third hypothesis. Efficiency and safety (besides comfort) are key optimization goals of ergonomics. In the other articles, I touch upon a project (related to virtual reality) with an iterative development process, in which ergonomic aspects were collected to improve the usability of the immersive environment.

Forming the thesis is novel/innovative in a meaning that involving users continuously to product development processes – especially in the medical equipment industry – is less conventional in Hungary. The ergonomic aspects within the topic of the product development were highlighted and was put more emphasis on in the dissertation.

**Hypothesis IV.** According to the users, medical devices implementing spin tube technique (which is an open system for reagents) are as justified as the blood group serological automatons using disposable tools (and applying a technique that is a closed system for reagents).

During my empirical researches I established contact with more than 40 colleges working at local institutions, dealing also with blood group serology. The devices used by the hospitals, territorial
or regional blood transfusion centers, central laboratories and non-profit medical ltd.’s cover the different techniques used in the field of blood group serology. Despite the spin tube technique is a universal(ly wide-spread) and standard technique applicable for all serology method, it is interesting to examine, whether a device implementing this technique has a reason for existence against the closed-system automatons using disposable tools, by the further development of the technology.

Related to my fourth hypothesis, I studied how the users judge the blood group serological devices being in the focus of my thesis. I collected indirect opinions, hence I did not ask whether the users think that the automatic development implementing spin tube technique was justified, as a separate question during the focus group sessions. I illustrated by descriptive statistics (average, median, center deviation, mean absolute deviation, standard deviation) and examples from transcripts that the users claim to keep the devices in question for different reasons for the future as well. The users had also positive opinion on the ACT’s considering the speed, material savings and free capacity etc. It was said that several types of tests could be conducted with these, and the measuring cost per test was favorable. The sensitivity of the technique was also emphasized by the users, and there were some being satisfied with the clarity of the results. Based on all of the above, the hypothesis is confirmed. I formulated the following thesis based on the above.

Thesis IV.: **According to the users, medical devices implementing spin tube technique (which is an open system for reagents) are as justified as the blood group serological automatons using disposable tools (and applying a technique that is a closed system for reagents). (B*)**

* The article linked to the forth thesis covers the differences between the open and closed system blood serology devices, lists the different techniques, and discusses the advantages and disadvantages of the devices implementing spin tube technique.

It is a novelty related to the thesis that the dissertation gives up-to-date information on how health professionals feel about the devices implementing open-system technique (compared with the ones with closed system).
**Hypothesis V.** The vast majority of the end-users find a fully automated (so-called walk-away) blood group serological device gratifying (in case of the proper operation of it) due to the minimization of the human tasks and responsibility.

According to the current technology, a blood serology device applying the highest level spin tube technique is able to provide the execution of the whole test (after the set-up) without human intervention, which opens new avenues in the history of these devices. It seemed to be worth examining the response given by the users to this.

During my *fifth hypothesis*, I analysed the responses given to the new blood serology device, the so-called “Advanced ACT”, investigated during the third phase of the focus group research. I got quite a mixed picture, over the content analysis of the transcripts, on how positive the opinion of the users on the new member of the device family, the fully automatic (i.e. walk-in type) device is. Although there were several advantages mentioned in the favour of it (for instance the release of capacity resulting from automation), such considerations came to the front (for instance the non-fulfilment of the claim for eye-control), which nuanced the picture. By the help of statistics, invoking the independent sample t-test, I finally concluded that the rather negative and the rather positive replies are yet significantly different, and the thoughts point to the latter. During the analysis of the second hypothesis, the topic of (lack) of eye-control was mentioned, and based on a concrete dialogue I tried to look beyond the explicitly expressed concern. I concluded that the users not necessarily insist on the eyes-control of the tested samples in any case, but to reach a technical solution, which provides good results, which can be easily evaluated at least with as much security as the user would on the basis of the eye analysis. Based on the above, the hypothesis was confirmed. I formulated the following thesis based on the above.

**Thesis V.:** *The vast majority of the end-users find a fully automated (so-called walk-away) blood group serological device gratifying (in case of the proper operation of it) due to the minimization of the human tasks and responsibility. (D*)

* The article linked to the fifth thesis presents the opinions and experiences of the users after their first encounter with the new product (walk-away type automaton).
The novelty related to the thesis is the (complex) survey on the newly created device, hence all its proceeds are necessarily such.

In the following table the relationship between the theses and hypotheses is summarized.

<table>
<thead>
<tr>
<th>Hypotheses</th>
<th>Research methodology</th>
<th>Result</th>
<th>Theses</th>
</tr>
</thead>
<tbody>
<tr>
<td>I.</td>
<td>content analysis, chi square test</td>
<td>partly confirmed, rewritten</td>
<td>I.</td>
</tr>
<tr>
<td>II.</td>
<td>content analysis, examples analyzed deeper</td>
<td>confirmed</td>
<td>II.</td>
</tr>
<tr>
<td>III.</td>
<td>content analysis, One-Way ANOVA</td>
<td>confirmed, with a little addition</td>
<td>III.</td>
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<tr>
<td>IV.</td>
<td>content analysis, descriptive statistics, examples</td>
<td>confirmed</td>
<td>IV.</td>
</tr>
<tr>
<td>V.</td>
<td>content analysis, independent-samples t-test</td>
<td>confirmed</td>
<td>V.</td>
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</table>

Several results and examples presented in the dissertation supports that it worth collecting the opinions and needs of the users by carefully designed and executed research methodology, and integrating these in the product development process. The focus group sessions, which took place in several phases, at the same time confirmed for me, that it worth not doing it by an ad hoc approach, but planning to incorporate it in the product development. As a result, and as a summary of the research, I improved the below product innovation model of Roozenburg and Eekels (1995)\(^2\) as a “scientific produce”.

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This model goes beyond the linear models, among others by the approach, that it presents the production, construction and marketing planning as processes to be performed in parallel. It is important to see that it also provides feedback arising from the product usage to the corporate strategy and corporate goals.

I developed the model on two points: on the one hand I split the feedback into two: for the information on the existing products, and information on the new products. I think these are to be integrated into different parts of the product innovation process, therefore the “information collected on existing product” branch out into two. Processing this information may have a value for a company in the development of the existing products, as well as may give input for generating new ideas.

In the model, on the other hand, I depicted the part on the collection and selection of ideas, and detailed how the feedback from the users and the market can be adopted in it. (This is shown in the following figure, in the blueish rectangle.)
Figure 4: Further developed product innovation model
Source: Own based on the model of Roozenburg and Eekels (1995)
IV. DIRECTIONS FOR FUTURE RESEARCH

The possible directions for future researches were already touched upon in the previous chapter. Beyond those, it would be worth for instance analyzing the nonverbal communication (by means of the video recordings of the focus groups) in order to clarify the results. It would be interesting to compare the dominant opinions of each group of participants along the three phases of the research: situations occurred in groups, interaction between participants could also be analyzed. Influencing factors could be taken a closer look at; and they could be involved in the analysis in various ways.

It could be analyzed related to hypotheses – when comparing the opinion of different groups of participants – up to what extent there was agreement within the focus groups. It would be interesting to analyze whether there were focus groups where the participants had rather different opinion; or whether the opinion of dominant participants prevails. Those could be analyzed by means of different statistical agreement methods, thus even more detailed analyses could be done.

The fourth hypothesis (i.e. whether a device implementing spin tube technique still has a reason for existence according to the participants) was confirmed by means of examples from the transcripts. The different aspects had the same weighting. It would worth having the factors weighted by a team of 3-5 experts, thus, statistical calculations could be carried out.

It would worth studying the product development process of other medical devices to see up to what extent the experience gained from the analysis of the ACT product line can be adapted into them.
V. PUBLICATIONS RELATED TO THE THESIS


