QFD BASED SOFTWARE FOR AN INNOVATIVE MEDICAL DEVICE ANALYSIS

Andreea Ionica, ***Ph.D. Associated Professor, University of Petrosani*****; Monica Leba,** ***Ph.D. Associated Professor, University of Petrosani*****; Remus Dobra,** ***Ph.D. Lecturer, University of Petrosani***

ABSTRACT
First there is presented the QFD methodology that was the basis for the software development. This methodology can be applied to any new product development (NPD) process, either hardware or software product. This software was then used for the evaluation of an innovative medical device developed by the authors and patented at national level. The QFD methodology was involved in all the development phases of the medical device starting from the customers' requirements capture and finishing with the evaluation of the resulting prototype.
KEYWORDS: *quality, biometric identification, innovation*

1. INTRODUCTION

Quality Function Deployment (QFD) is well known to be the method that transforms the user requirements into design quality, the method that translates the client's "voice" into engineering characteristics. This is the result of combining Akao's work [1] in quality assurance and quality control points with function deployment from value engineering. The main goals in implementing QFD method are: discover the spoken or unspoken users' needs, translate these needs into quality characteristics, built and deliver quality products and services by focusing on customer satisfaction [9]. The QFD method is also known as the method applied for New Product Development (NPD) process, in this case for an innovative medical device based on biometric identification. The biometric identification system for emergency cases uses a method of storing relevant medical information based on biometric identification, generating medical records that allow the emergency medical personal to track the patient medical history and identify problems or patterns that may help determine the course of health care. The innovative product eliminates the classical methods insufficiencies by optimizing the time response, facilitating access and by ensuring an increased security regarding the primary medical information for emergency situations and represents a new storage approach of the primary healthcare information based on biometric identification by means of fingerprint sensor. The device referred to is the subject of an OSIM patent registered (A/ 00167/2014) and is designed for relevant medical information storage [6].

2. THE QFD METHODOLOGY

The study presents the use of QFD method applied on a biometric identification system for emergency cases.

We present some key elements that prove the applicability of the QFD method in the context of NPD. The application of QFD to NPD requires that the voice of customers is integrated in every stage of product planning to ensure customer satisfaction [1]. The first step towards understanding customers' needs is to identify attributes and customer consequences, which are a result of using attributes.

The interviews and questionnaires generate the customers' requirements matrix CR_n consisting of all the identified requirements grouped in priority classes (figure 1) [5]. The design team establishes the main quality characteristics of the innovative product that meet the users' expectations. As a result the quality characteristics matrix QC_m is created and also contains the achievement difficulty level for each characteristic. Each characteristic is related to technical implementations and has well defined purpose. The influences matrix $ICQ_{n\ x\ m}$ contains the way of distributing the users' requirements on quality characteristics, and the correlation matrix $TQC_{m\ x\ m}$ the interdependencies between the characteristics. The technical team implements the characteristics of the product, and the testing team, after applying different methods of evaluation and validation, determines the achievement level of each characteristic and thus the achievement matrix AQ_m. The achievement matrix and the influences matrix determine the relationship matrix $RCQ_{n\ x\ m}$. This matrix shows the accomplishment level of the customers' requirements by the implemented quality characteristics. Based on all these matrices we can compute the offset [7].

The paper presents the application of QFD method for analyzing customer requirements on the implementation of a medical device used in emergency medical situations. From the above mentioned steps, we focus on identifying the customer needs and requirements.

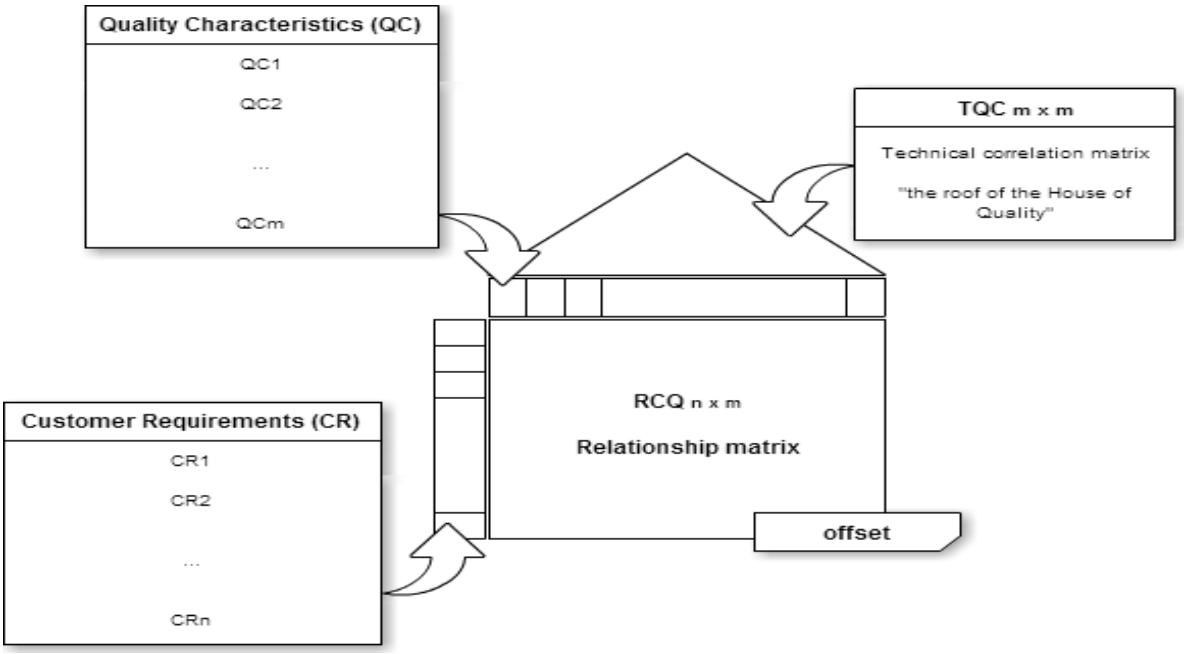


Fig.1. QFD methodology [7]

3. MAIN FINDINGS AND RESULTS

Customer requirements capture represents the first step of applying QFD method. We used this technique of the questionnaire applied on 50 respondents. The main categories of respondents are presented in fig. 2.

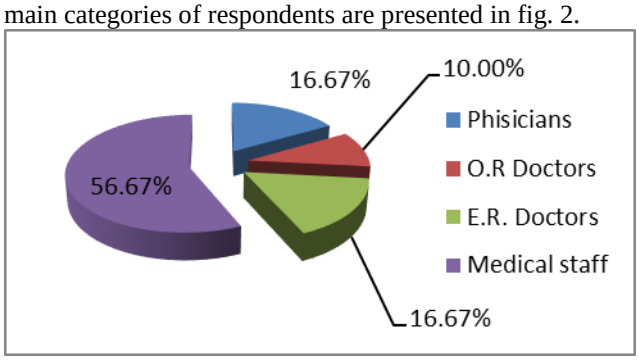


Fig. 2. Categories of respondents

All respondents consider that the device would be important for the patients benefit and would improve significantly information management by: decreasing the time to identify patients, decreasing the time for the investigations and ensuring prompt treatment.

Further we present the analysis and interpretation of customer requirements for the innovative medical device.

In Table 1 are presented the results of the assessment criteria for different levels of importance (1 most important, 8 the least important).

In Figure 3 is presented the ranking of respondents on the basis of answers given in the questionnaire.

Table 1

Criteria	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Autonomy	*0.00%*	*13.33%*	*13.33%*	*16.67%*	*20.00%*	*16.67%*	*0.00%*	*20.00%*
Easy to use	*3.33%*	*6.67%*	*13.33%*	*26.67%*	*40.00%*	*10.00%*	*0.00%*	*0.00%*
Efficiency	*6.67%*	*26.67%*	*23.33%*	*13.33%*	*20.00%*	*10.00%*	*0.00%*	*0.00%*
Safety and security of data	*46.67%*	*26.67%*	*16.67%*	*0.00%*	*0.00%*	*10.00%*	*0.00%*	*0.00%*
Portability	*13.33%*	*13.33%*	*0.00%*	*23.33%*	*10.00%*	*13.33%*	*26.67%*	*0.00%*
Accuracy	*0.00%*	*13.33%*	*0.00%*	*20.00%*	*10.00%*	*26.67%*	*20.00%*	*10.00%*
Affordable price	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*13.33%*	*33.33%*	*53.33%*
Insurance warranty, service, update	*30.00%*	*0.00%*	*33.33%*	*0.00%*	*0.00%*	*20.00%*	*0.00%*	*16.67%*

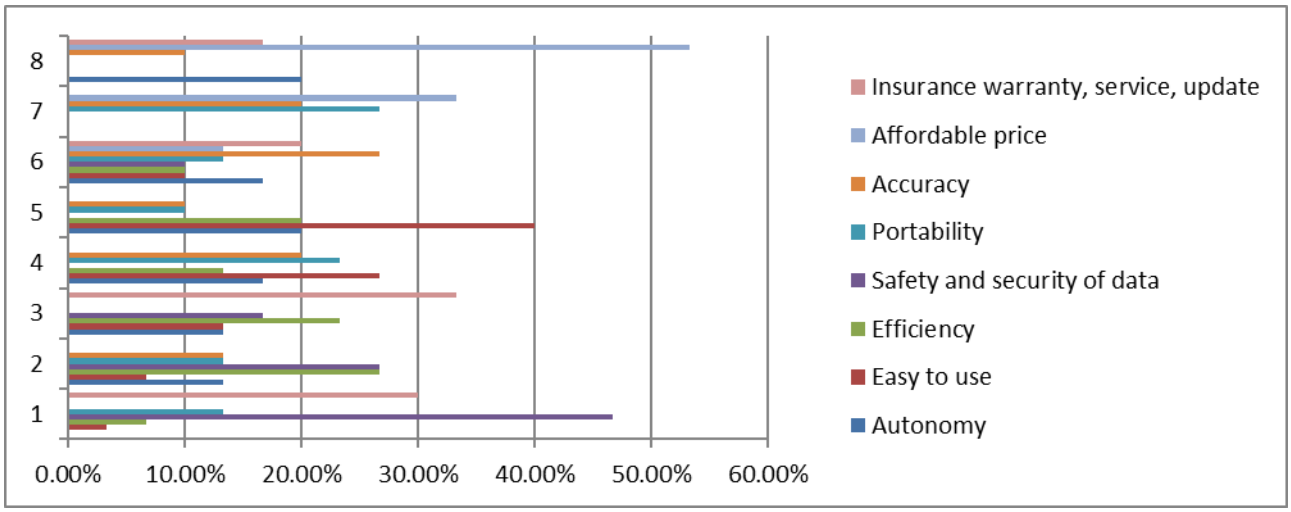


Fig 3. The ranking of the respondents based on the criteria

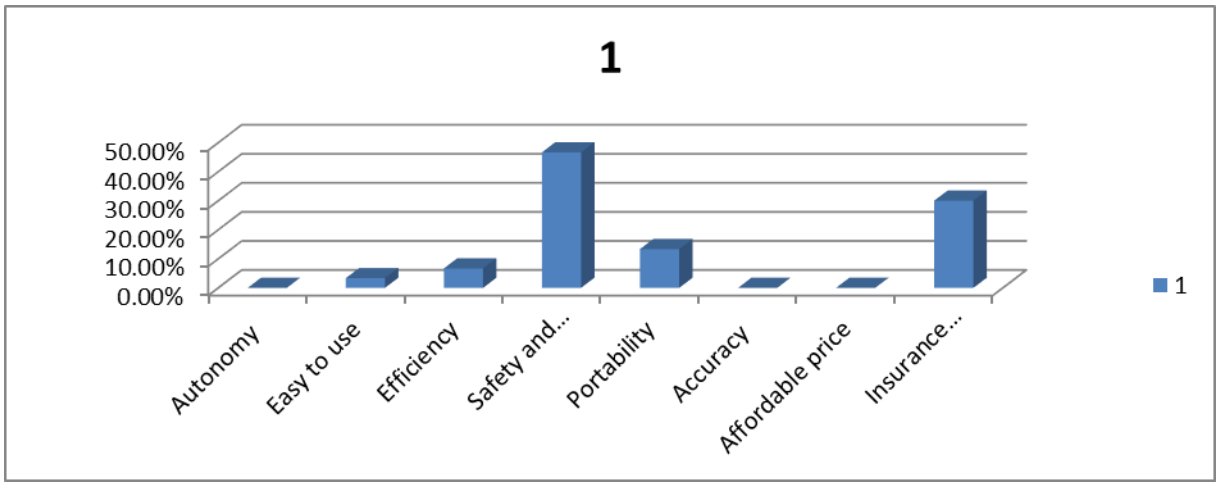


Fig 4 a. The most important criteria

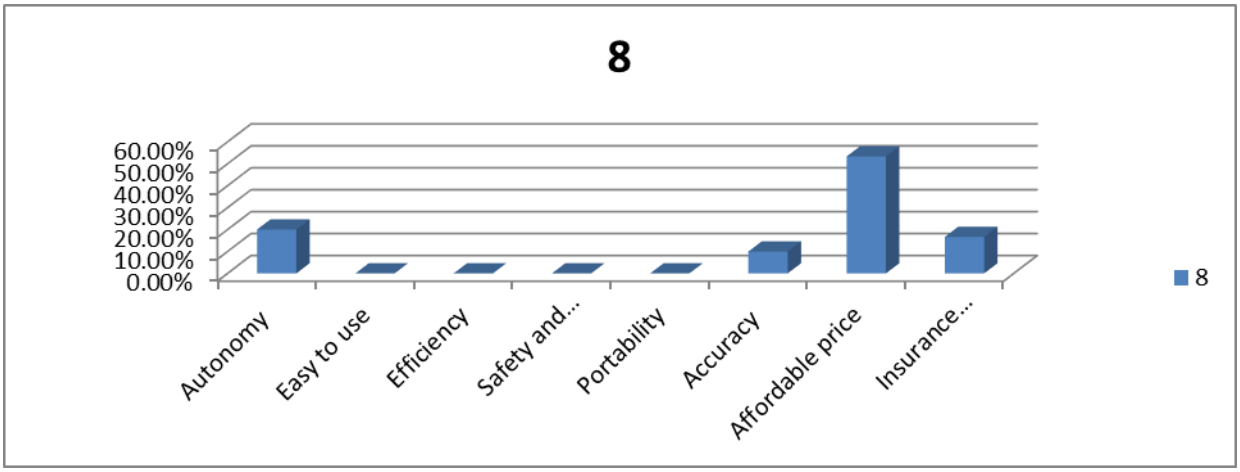


Fig. 4 b. The least important criteria

The highest importance (1) is attributable to *Safety and security of data* criterion (46.67%), followed by *Insurance warranty, service and update* (30.00%) and *Portability* (13.33%). The following criteria: *Affordable price* (53.33%), *Autonomy* (20.00%) and *Insurance warranty, service and update* (16.67%) are situated on the last places. The last criterion, as can be observed is found among those considered very important (Fig 4 a and b). This is because the respondents were classified into four categories, and the responses are linked to specific activities submitted. In this context we considered relevant for our research, the representation of the results for each level of the respondents category (Fig.5 a and b).

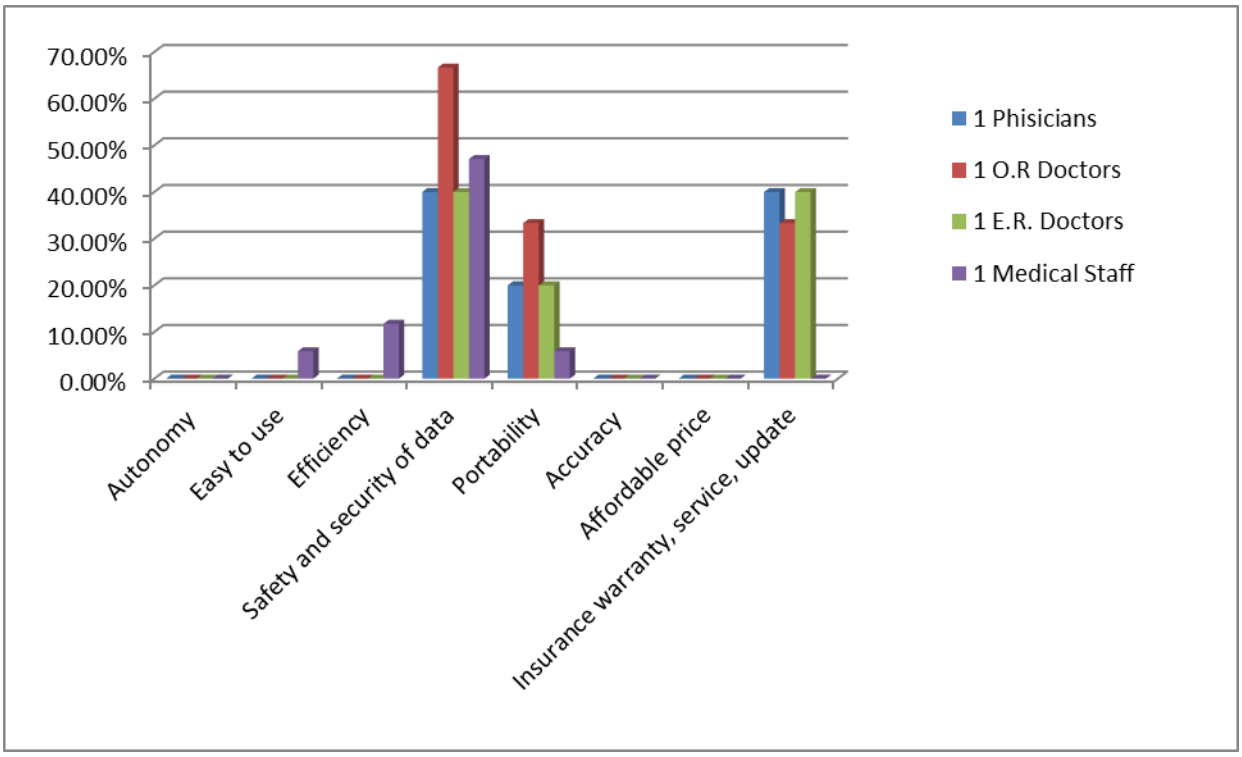


Fig 5.a. The relationship between criteria and categories of respondents

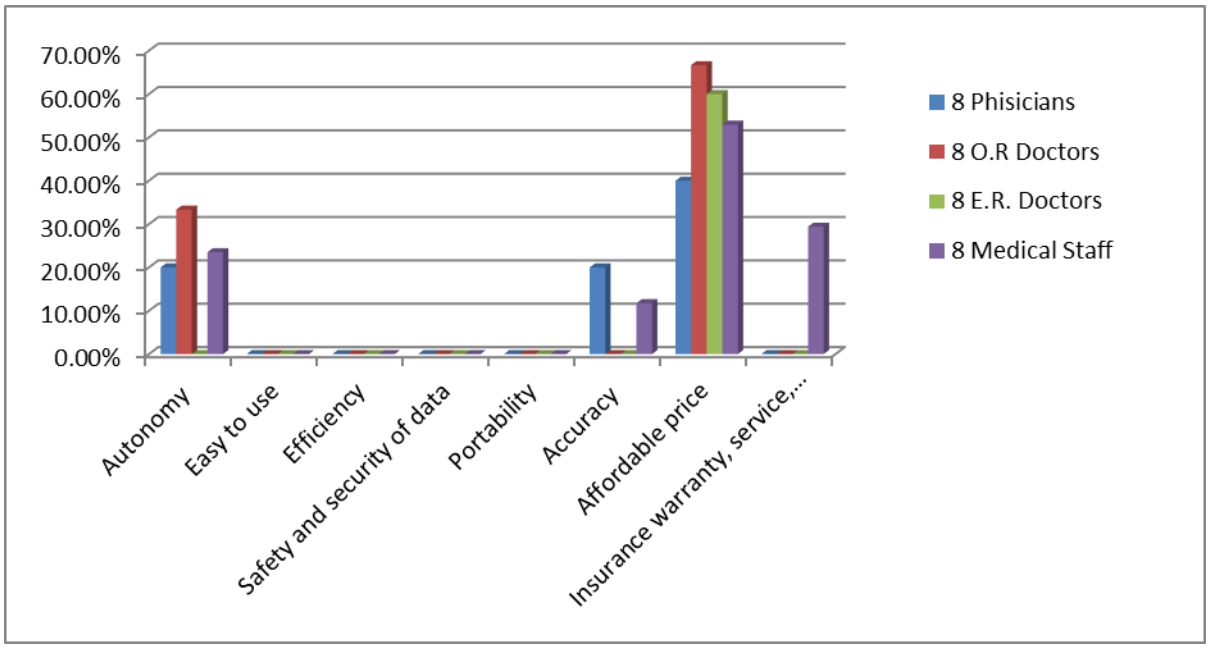
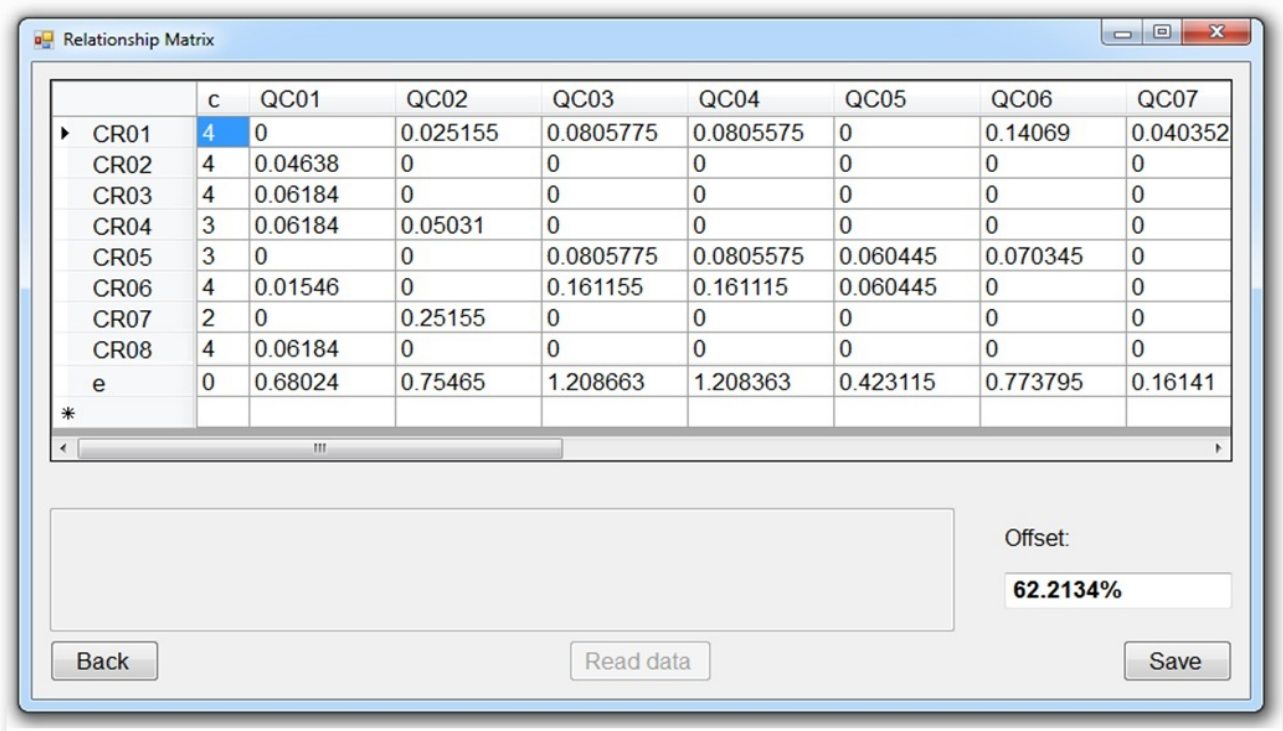


Fig 5.b. The relationship between criteria and categories of respondents

The highest degree of importance is given by the O.R. Doctors category of respondents for *Safety and security of data* criterion.

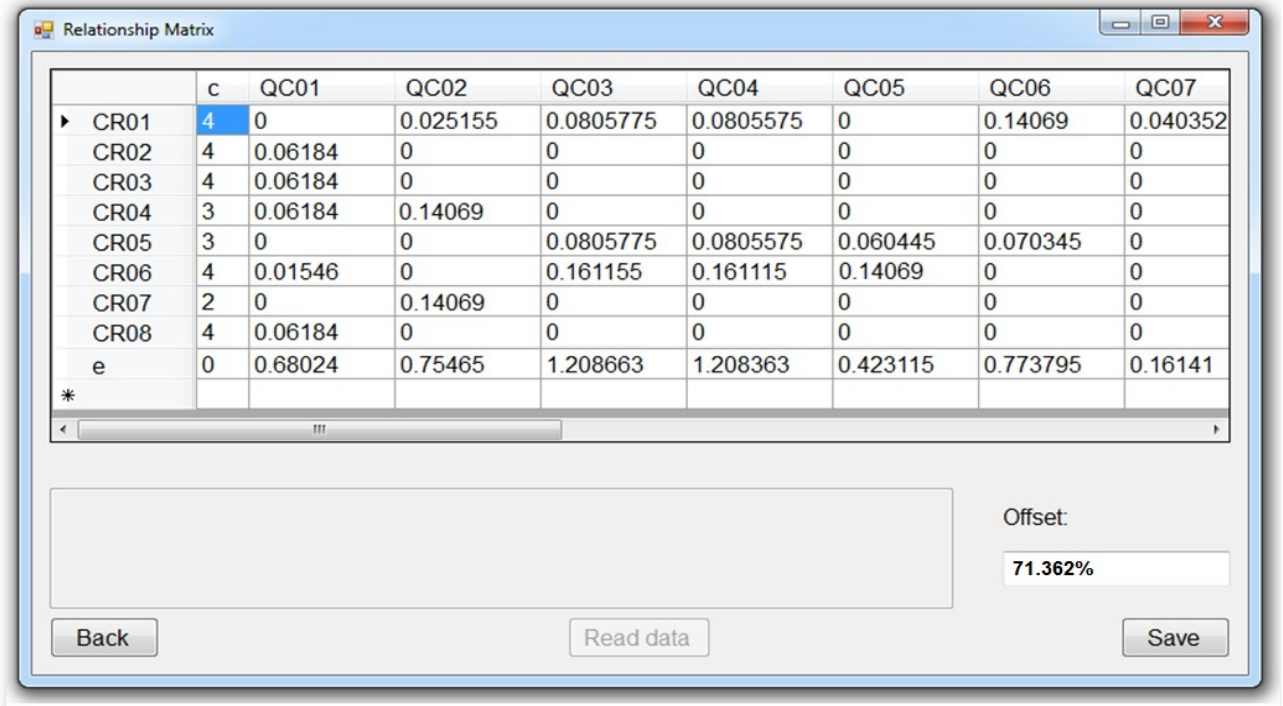
It follows from the representation that the least important criteria for the respondents, for any category of respondents, is the price compared to the usefulness of the device.

Next we present the application of QFD based software tool for two situations: the initial capture of requirements in the design phase (Fig. 6) and the second case after the prototype phase (Fig. 7). The software tool generates different values of the global index providing the basis for analyzing the device as a measure of performance.



	c	QC01	QC02	QC03	QC04	QC05	QC06	QC07
CR01	4	0	0.025155	0.0805775	0.0805575	0	0.14069	0.040352
CR02	4	0.04638	0	0	0	0	0	0
CR03	4	0.06184	0	0	0	0	0	0
CR04	3	0.06184	0.05031	0	0	0	0	0
CR05	3	0	0	0.0805775	0.0805575	0.060445	0.070345	0
CR06	4	0.01546	0	0.161155	0.161115	0.060445	0	0
CR07	2	0	0.25155	0	0	0	0	0
CR08	4	0.06184	0	0	0	0	0	0
e	0	0.68024	0.75465	1.208663	1.208363	0.423115	0.773795	0.16141

Fig. 6. The overall index for the design phase



	c	QC01	QC02	QC03	QC04	QC05	QC06	QC07
CR01	4	0	0.025155	0.0805775	0.0805575	0	0.14069	0.040352
CR02	4	0.06184	0	0	0	0	0	0
CR03	4	0.06184	0	0	0	0	0	0
CR04	3	0.06184	0.14069	0	0	0	0	0
CR05	3	0	0	0.0805775	0.0805575	0.060445	0.070345	0
CR06	4	0.01546	0	0.161155	0.161115	0.14069	0	0
CR07	2	0	0.14069	0	0	0	0	0
CR08	4	0.06184	0	0	0	0	0	0
e	0	0.68024	0.75465	1.208663	1.208363	0.423115	0.773795	0.16141

Fig. 7. The overall index for the prototype phase

4. CONCLUSIONS

The analysis and the interpretation of results obtained in the customers' requirements capturing phase led to the conclusion of the utility and necessity of extending the research on the medical device.

This paper presents only a phase of applying the QFD based Software tool, being part of a wider research finalized with a patent registration.

Otherwise, the QFD based software designed tool determines an overall index as a measure of the device performance that can be used for improving the medical device based on users' requirements and quality characteristics.

5. REFERENCES:

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