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Managing requirements for the development of a novel elbow rehabilitation device

Aline Marian Callegaro *, Carla Schwengber ten Caten, Raffaela Leane Zenni Tanure, Amanda Sória Buss, Márcia Elisa Soares Echeveste, Carlos Fernando Jung

Product and Process Optimization Laboratory, Graduate Program of Industrial Engineering, Federal University of Rio Grande do Sul, Avenida Osvaldo Aranha, n. 99, 5th floor, 90035-190 Porto Alegre, RS, Brazil

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ABSTRACT

The development of new technologies for healthcare must take into consideration customer requirements from different stakeholders. The Voice of the Customer must be identified, analyzed and organized. This study aims to present a new approach of managing requirements from different product value chain stakeholders for a novel elbow rehabilitation device development. The Customer Value Chain Analysis tool was used to identify the product value chain stakeholders and the Quality Function Deployment tool to analyze and prioritize these requirements. The development is described in accordance with the engineering requirement process adapted to this case: 1) elicitation: the requirements come from the literature; benchmarking; questionnaires applied to all parties identified by Customer Value Chain Analysis application; 2) analyses: requirements were understood, and their overlaps, conflicts and prioritization were done by means of Quality Function Deployment (quality, product and part characteristics matrices); and 3) documentation: the identified construct of requirements were: ergonomics, functions, aesthetics, handling, materials, components/elements. The main parts that must be prioritized were: arm support, forearm support, support shaft, joystick, and support base. The association of these two tools is a novel and successful approach of identify different product value chain stakeholders and prioritize technical requirements for health product development.

1. Introduction

Successfully launching innovations is time sensitive and requires strategic and future-oriented thinking (Kolominsky-rabas et al., 2015). The different knowledge-generating paradigms drive innovation systems (Ivanova and Leydesdorff, 2015). The innovation process has often been represented as a linear process which funnels customer needs through business and process filters. This method may be appropriate for some consumer products, but in the medical device industry, there are some inherent limitations to the traditional innovation funnel approach.

In the medical device industry, there are a number of stakeholders who need to have their voices heard throughout the innovation process (Ana et al., 2013). Insights from many areas of science, engineering, medicine, the humanities, business and law are needed for the success of new medical devices. A clear, deep and unbiased understanding of the healthcare need for which a solution is to be developed is the critical starting point (Yazdi and Acharya, 2013). The standards of the country where the device is being developed are a mandatory point that should also be taken into consideration during the innovation process of a new medical device (Kolominsky-rabas et al., 2015).

Most of the models of product development process present a step of identification of ideas and opportunities (Pahl et al., 2007), followed by concept development and detailed design, up to the product or service launch and monitoring in the market. The product life cycle ends with the product (and its parts) discontinuity and recycling (Marx and Paula, 2011). The product development process should be formalized, clarifying the product, process and resource requirements.

The requirement is a feature that the system-product must have in order to satisfy a need or to achieve a stakeholder goal, being qualified by measurable conditions and bounded by restrictions. Therefore, the analysis of requirements from different stakeholders is an essential step in the innovation process of medical devices. However, inherent difficulties are present in the process of discovering and identifying stakeholders and their needs, and documenting these in a form that is amenable to analysis, communication, and subsequent implementation (Nuseibeh and Easterbrook, 2000).

Some tools have been developed to assist the process of allocating the requirements to product parts for incremental and radical projects, such as surveys, Customer Value Chain Analysis (CVCA) and Quality Function Deployment (QFD) tools. The CVCA is a strategic and tactical tool which was implemented from the organization business model that establishes a value map, in the product definition phase that

* Corresponding author.
E-mail addresses: nimacall@gmail.com (A.M. Callegaro), carlacaten@gmail.com (C.S. Caten), raffaelat@gmail.com (R.L.Z. Tanure), mandikabuss@gmail.com (A.S. Buss), echeveste.mar@gmail.com (M.E.S. Echeveste), carlosfernandojung@gmail.com (C.F. Jung).

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contributes to a comprehensive identification of relevant stakeholders, their relationships with each other, and their role in the product life cycle. Thus, the CVCA tool adds value to the requirements identification in the project process, because it can be used for requirements elicitation and rating. It helps the innovation process for developing new medical devices, and shows resources and new ideas for novel products. The CVCA tool output can be the input for other tools, such as QFD (Donaldson et al., 2006), that aims at deploying these requirements throughout the product development process.

QFD tool was proposed to collect and analyze the Voice of the Customer (VoC) in order to develop products with higher quality to meet or surpass customer needs. The primary functions of QFD are product development, quality management, and customer needs analysis. Customer needs analysis is always the very first step of a QFD process. The QFD functions have been expanded to wider fields such as design, planning, decision-making, engineering, management, teamwork, timing, and costing (Chan and Wu, 2002).

Thus, this paper hypothesizes that the association of CVCA with QFD can assist in innovation and consequent creation of value for health products. The CVCA tool allows the process mapping, helping understanding the business unit, product value chain and identification of critical stakeholders (Donaldson et al., 2006); while the QFD method assists the requirements quantification to align concepts and resources, increasing the team ability to recognize the diverse product technical requirements, and their prioritization to define the product.

Based on this context, a research question was formulated: What could be a new and appropriated approach to manage requirements for the development of a novel elbow rehabilitation device in a more comprehensive way using CVCA tool associated with QFD, described in accordance with the requirements engineering process? This paper aims to present a new approach of requirements managing from different product value chain stakeholders for the development of a novel elbow rehabilitation device. The structure of this paper comprises the following sections: 1) the second section provides related literatures in new product development process, 2) the third section is for materials and methods with a model associating CVCA with the adapted QFD tool; 3) the fourth section presents (ii) study results of the development of a novel rehabilitation device, and the 4) (iii) the fifth section is a discussion with this model developed for the collection and prioritization of the requirements for the development of a novel elbow rehabilitation device; and 5) the last section provides a concluding remarks.

2. Literature reviews

Stakeholders are people who directly or indirectly use a system or the information it provides, as well as essential system characteristics such as performance, security, and dependability (Sommerville, 2005). Each stakeholder has diverse and unique needs, and the needs of one may highly affect the needs of another, and the relationships between them may be tenuous (Ana et al., 2013). No single individual or discipline alone has the ability to successfully create, develop, and implement an effective solution for a new product development process (Yazdi and Acharya, 2013). Moreover, the marketing assessment of potential consumers is an important step in new device development process for the health area (Marx et al., 2010).

Before developing any system, one must understand its target customer and technical requirements. At this moment, the objective of the system is being projected, and it is important to know how its use can support the goals of the individuals or businesses that would pay for that system. This involves understanding the application domain; the system operational constraints; the specific functionality required by the stakeholders; and essential system characteristics such as performance, security, and dependability (Sommerville, 2005).

Stakeholders (including paying customers, users, and developers) may be numerous and distributed. Their goals may vary and conflict, depending on their perspectives of the environment in which they work and the tasks they wish to accomplish. Their goals may not be explicit or may be difficult to articulate, and, inevitably, satisfaction of these goals may be constrained by a variety of factors outside their control (Nuseibeh and Easterbrook, 2000), for example, the balance between personalization and standardization of the health technology (Peine and Moors, 2015).

The management of requirements is a current research topic. User preferences need to be taken into account in order to enable the design of devices that will gain acceptance both in clinical and home settings. One way of understanding user preferences is through literature review, which has been used to identify, retrieve, and assess all studies evaluating user preferences from patient and clinician perspectives (Bergmann and McGregor, 2011). However, few researchers have identified that only the literature review is not enough to discover the customer preferences. In order to fill this gap, a few studies on requirements engineering have been published (Sommerville, 2005), as a new process to balance the stakeholders' voices (Ana et al., 2013) and a systematic proposal to manage requirements for the development process of sustainable products (Marx and Paula, 2011).

Hoffmann et al. (2014) point of view is that the requirements are developed based on the given facts of the environment and the mission to be achieved. In the course of a project, they become more concrete, more detailed, and also more complex. The closer the specification approaches atomic requirements, the more complex the relationship between them becomes: the requirements changes must be handled, the status of requirements must be updated according to the project phase, and tracing to other development artifacts should be established. Based on all of this, there is still a need for new studies that find good approaches to manage requirements, especially for the health product development.

3. Material and methods

This research is classified as a quali-quantitative study. Based on its main goal, the research is classified as an exploratory study, because it aims to offer more familiarity with the problem, making it more explicit (Gil, 2002). A model associating CVCA (Tanure et al., 2013) with the adapted QFD tool (Ribeiro et al., 2001) was developed to analyze the product value chain stakeholders, identify their needs, and analyze and prioritize their requirements, as shown in Fig. 1.

Both tools were analyzed by the research team and applied in an integrated manner. The CVCA tool stages were developed to carry out the value chain analysis and identify the product value chain stakeholders. The CVCA tool has seven stages: 1) definition of the initial business model and its assumptions; 2) delineation of the pertinent parties involved with the product; 3) determination of how the parties are related to each other; 4) identification of the relationships between the parties by defining flows between them; 5) analysis of the resulting Customer Value Chain to determine critical customers and their value propositions;6) inclusion of the information in Product Definition Assessment (PDA); 7) use of CVCA results in the product (Donaldson et al., 2006). The CVCA's seventh stage consists on using the results of the value network; the first five steps related to the customer value chain were developed in this study.

In order to analyze, define and prioritize the requirements, the QFD tool was deployed in three matrices: quality matrix, product matrix, and characteristics of the parts matrix (Buss et al., 2012). Results of CVCA and QFD applications were organized and described in accordance with the engineering requirement process adapted to this case: elicitation, analysis, and documentation (Sommerville, 2005). The elicitation and analysis are shown in this Section 3, and the documentation is the results shown in Section 5.

3.1. Elicitation

The requirements came from primary and secondary sources, as shown in Fig. 2. The primary sources include interviews with the

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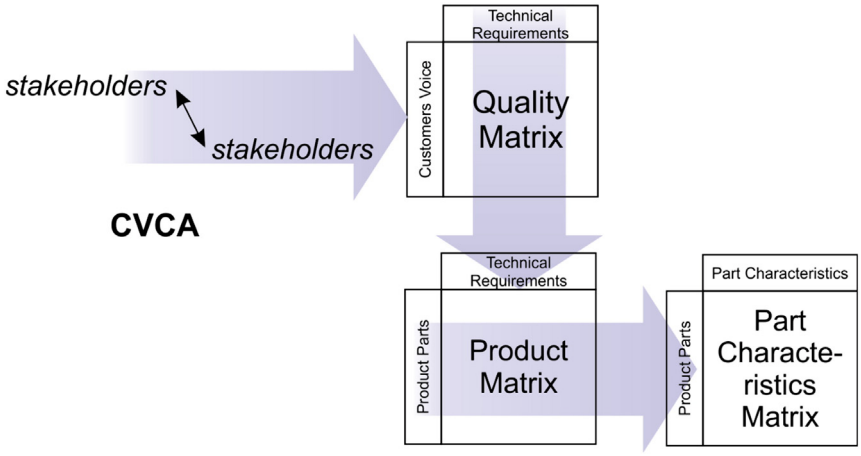

Fig. 1. Model integrating Customer Value Chain Analysis with Quality Function Deployment tools. *CVCA: Customer Value Chain Analysis. Source: primary.

following product value chain stakeholders: patients, graduate students of the product development area, experts, and representatives of companies operating in the area of medical products. The critical customers identified by the CVCA answered a qualitative questionnaire and later filled in a quantitative questionnaire. Data collection was done as shown in previous studies published by the research team (Buss et al., 2012; Callegaro and Jung, 2011).

Other requirements came from 1) a focus group with fifteen health care professionals: physical therapists and occupational therapists who had ever worked with CPM machines for elbow and/or forearm rehabilitation, and 2) a brainstorming with the team research, engineers and graduate students of biomedical and industrial engineering; 3) secondary sources such as a qualitative study made with physical therapists, patients and physicians who had ever worked/used similar machines for upper and lower limb rehabilitation (Callegaro et al., 2011c), a benchmarking study (Callegaro et al., 2011a), and a literature review (Callegaro et al., 2011b); other literature studies, standards and laws.

3.2. Analyses

The CVCA was applied for the identification of the critical stakeholders of a new health device. The input of CVCA application is shown in Fig. 3 (Tanure et al., 2012a). The critical stakeholders were identified as clinical, product, process and reliability engineers; project and product managers; financial sector staff; quality system and regulatory affairs staff, internal and external to the organization. Physical therapists, occupational therapists, physicians and patients are related to the clinical engineering and regulatory affairs. Thus, the researchers also considered these users as critical stakeholders and also highlighted that they must necessarily be considered in a direct mode at the early stage of the project.

Stakeholders' needs were collected and attributes were deployed and prioritized. Customer requirements and technical requirements were understood, their overlaps, conflicts and prioritization were done by means of QFD tool (Tanure et al., 2012b). The QFD model used by this research was composed by three matrices: quality matrix, product matrix, and part characteristics matrix, as shown in the documentation subsection (Tanure et al., 2013).

4. Results

A conceptual model that integrates the CVCA tool with QFD tool, as shown in Fig. 1 was developed and applied for the development of a novel rehabilitation device. Its application is described following the requirements engineering. The CVCA input was written like a business model, as shown Fig. 3. The critic customers were highlighted and the customer requirements, product quality and technical requirements were deployed in matrices with their quantitative prioritization.

4.1. Customer requirements

The demanded quality survey done by the critical customers, identified in the CVCA output, showed that the primary customer requirements, according to the product relative importance, were ergonomics, functions, aesthetics, handling, material, components/elements, as shown in Table 1. The secondary level of customer requirements for each primary level was: ergonomics – effective performance, patient and operator safety, anthropometric adjustment, and patient comfort; functions – simple and intuitive interface, physiological passive amplitude, multiple functions, applicable to various joints; aesthetics - compact and portable, organic design, innovative, discrete; handling – easy to assemble, install, configure, adjust and use, easy to transport (accessory), dismountable, and easy to store; material – resistant to conditions of use and maintenance, soft, breathable and non–allergenic to skin, trustworthy, easy to clean/antisepticize; components/elements – low weight of the equipment, safe components, reduced maintenance (not requiring specific technical care), replacement parts guaranteed.

Table 1 presents the qualitative requirements identified with those respective weights. The weights related to the secondary level items were obtained from the final issue of the quantitative questionnaire, in which respondents should establish a ranking for the secondary characteristics. The weights for the tertiary level were obtained by averaging the respondents.

After calculating the weight of each variable in the tertiary level, we calculated the relative weight the importance of each variable in relation to the weight of its secondary level. This is the Index Demanded-quality importance index (IDi) which was adjusted using two different factors. The first factor is used to consider the relevance of each item, considering its importance to the company strategy (Ei), while the second factor is used to consider the company competition position (Mi) in the market in comparison to a benchmarking organization. The result is the Demanded-quality Importance Index Adjusted (IDi^*) calculated as shown in Eq. (1).

$$IDi^* = IDi \times \sqrt{Ei} \times \sqrt{Mi} \quad (1)$$

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	Requirements source classification	Primary				Secundary			
	Evidence source (Information)	Interviews with patients	Interviews with graduation students	Interviews with experts (physical therapists, physicians, occupational therapists, biomedical engineering)	Interviews with company representants	Literature (papers, books, dissertations, patentes)	Standards/laws	Benchmarking	Team knowledge
Visual aspects	Innovative		X	X				X	X
	Organic design		X						
	Compact and portable	X	X	X		X			X
	Discreet design		X						
Technology	Soft, breathable, and non-allergic contact surface	X		X		X		X	X
	Reliable technology	X	X	X	X		X		X
	Easy hygienization and disinfection	X		X			X		X
	Use conditions and maintenance resistance		X	X		X	X		
	Safety	X	X	X	X	X	X		X
	Low weight	X		X				X	X
	Guaranteed replacement service on parts		X	X	X				X
	Reduced maintenance (specific technical care is not need)	X		X					X
Functionality/ Reliability	Ease of storage	X	X	X					
	Easy transport (accessory to facilitate transportation)	X	X	X					X
	Demountable	X	X	X	X	X			X
	Easy assembly, installation, setup, adjustment and use	X		X	X	X	X	X	X
	Anthropometric adjustment	X		X		X		X	X
	Patient and operator safety	X	X	X	X	X		X	X
	Patient's best comfort	X	X	X	X	X		X	X
	Effective performance		X	X	X	X	X		X
	Physiologic Range of Motion (RoM)			X		X		X	X
	Multiple functions		X	X					
	Applicable to multiple joints			X					
	Simple and intuitive interface	X	X	X	X	X		X	X

Fig. 2. Requirements mapping.
Source: primary.

4.2. Technical requirements

Each secondary level of customer requirement has been transformed into a product technical requirement (quality characteristics). The product quality requirements were prioritized by means of the quality matrix application. The results showed the need of prioritizing the following decreasing order of the product technical requirements: material percentage (%), anthropometric adjustment (centimeters); system and movements reliability level (%); flexibility degrees of the transportation system (%); modular system (parts number); life cycle (years); level of maintainability (%); level of facility of assembling, installing, configuring, adjusting and using (%); applicability to various body joints (number of joints); compact size of the device (cubic centimeters – cm^3); device weight (grams); level of storage (%); risk points (%); effective performance index (%); quality standards (%); comfort level of the material contacting the skin (%); degrees of the physiologic passive range of motion (°); reliability level of the material (%); level of compatibility with other devices (%); replacement parts guaranteed (number of parts); possibility of assisted, active, and resisted movements (number of parameters); resistance to cleaning products (%); equipment aesthetic acceptability degree (%); and innovative type (radical or incremental).

Fig. 4 shows the importance of quality characteristics (IQj). IQj was calculated according to the Eq. (2). This calculation considered the intensity of the relationship between the demanded quality items and quality characteristics ($DQij$), as well as the relative importance of demanded quality (IDi^*).

$$IQj = \sum_{i=1}^{n} IDi^* \times DQij \tag{2}$$

The intensity of the relationship between the items of the demanded quality, the quality characteristics and the relative importance of the demanded quality was considered. The index importance of quality characteristics (IQj^*), as shown in Eq. (3), was adjusted. A correction factor by assessing the difficulty of acting on the quality characteristics

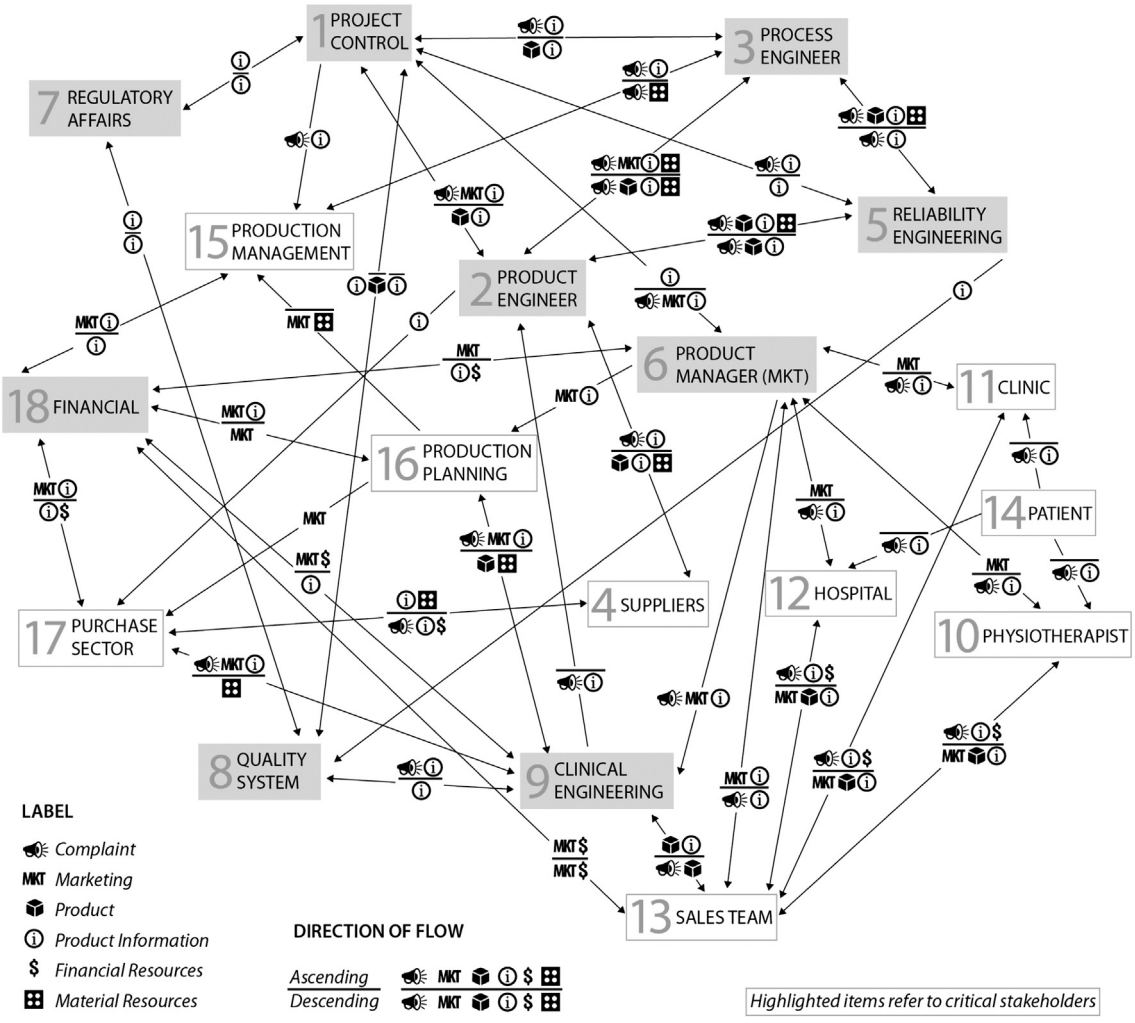

Fig. 3. Customer Value Chain Analysis Input - related stakeholders, flows and analysis of the product value chain.
Source: primary.

(*Dj*) and a competitive assessment with respect to technical characteristics (*Bj*) was used for the adjustment.

$$IQj^{*} = IQj\sqrt{Dj} \times \sqrt{Bj} \tag{3}$$

4.3. Product parts and part characteristics

The results of the product matrix applications showed the need of prioritizing the following decreasing order of the product parts: arm support, forearm support, support shaft, joystick, support base, mechanical system, electronic system, and software. The Level of Importance of the Quality Characteristics (*IPi**) (Fig. 4) was adjusted using a correction factor by evaluating the difficulty of making modifications (*Fi*) and the time required for modifications (*Ti*).

After the deployment and the prioritization of the parts, characteristics of parts matrix were filled and the greatest parts were crosschecked with their quality characteristics. Thus, it was possible to identify which characteristics must be controlled in the critical parts to provide the product quality. Through characteristics of the parts matrix, the need to prioritize the following descending order of the product part characteristics was observed: arm support dimensions (centimeters), shoulder angle adjustment (degrees), forearm support anthropometric adjustment, arm and forearm support congruence, shaft thickness (millimeters), height adjustment, support shaft angle (90°), joystick dimensions (centimeters), support base leveling, mechanical system operating parameters, electronic system operating parameters, arm support weight (grams), arm support anthropometric adjustment, forearm support dimensions (centimeters), forearm support weight (grams), support shaft dimensions (centimeters), support shaft weight (grams), programming flexibility (%), joystick weight (grams), support base dimensions (centimeters), support base weight (grams). As the product matrix, the Level of Importance of the Quality Characteristics (*IPi**) was adjusted using a correction factor by evaluating the difficulty of making modifications and the time required for modifications.

5. Discussion

A conceptual model that integrates the CVCA tool with QFD tool, which results from the applications, was described following the requirements engineering to collect and prioritize requirements for the development of a novel elbow rehabilitation device. In applying the CVCA, the critical customers identified were clinical engineers, product engineers, process engineers and reliability engineers; project and product managers; financial sector staff; quality system and regulatory affairs staff, internal and external to the organization. According to the organization functional managers interviewed, the end users were: physical therapists, occupational therapists, and physicians, while patients have their interests covered indirectly by other stakeholders such as clinical engineers and regulatory affairs staff. Thus, the researchers also see these users as critical stakeholders and highlighted

Table 1
Stakeholder requirements.
Source: primary.

Primary costumer requirements	Rate secondary level	Secondary customer requirements	*IDi**
Aesthetics	0,179	Innovative	0,0388
		Organic design	0,0437
		Compact and portable	0,0662
		Discreet design	0,0184
Material	0,151	Soft, breathable and not allergic surface skin contact	0,0511
		Trustworthy	0,0410
		Easy to clean/antisepticize	0,0361
		Resistant to conditions of use and maintenance	0,0534
Components/elements	0,130	Safe components	0,0491
		Low weight of the equipment	0,0540
		Replacement parts guaranteed	0,0276
		Reduced maintenance (do not require specific technical care)	0,0399
Handling	0,169	Easy to store	0,0267
		Easy to transport (accessory)	0,0427
		Dismountable	0,0344
		Easy to assembly, to install, to configure, to adjust and to use	0,0486
Ergonomics	0,191	Anthropometric adjustment	0,0478
		Patient and operator safety	0,0488
		Patient's comfort	0,0458
		Effective performance	0,0488
Functions	0,179	Physiological passive amplitude	0,0467
		Multiple functions	0,0435
		Applicable to various joints	0,0367
		Simple and intuitive interface	0,0572

that they must necessarily be considered in a direct mode at the early stage of the project, as well as in verification tests of the final product in a more advanced stage.

Capelli et al. (2012) considers essential to understand the information about each individual patient characteristics and the interactions between the device and the patient's anatomy and function. Such information is important to ensure safe device design for the majority of medical applications. The findings of our study showed the model application allowed to identify different stakeholders using the proposed systematic approach. This new approach makes us to believe its inputs probably improve the development process of a novel medical device as soon as the customer different points of view could be taken into account. Consequently, the device can be well aligned to the customer requirements.

A similar study showed a spiral innovation process for the development of a medical device, which considers three distinct stakeholder voices: the voice of the customer, the voice of the business, and the voice of the technology. The process presented is a case study focusing on the front-end redesign of a class III medical device for an orthopedics company. Starting from project initiation and scope alignment, the process describes four phases (Discover, Envision, Create, and Refine), and concludes with value assessment of the final design features (Ana et al., 2013). While this study reports a front-end redesign, the results of our study reports technology inputs for the development process of a novel medical device.

In accordance with this discussion, Yazdi and Acharya (2013) point of view must be highlighted: bridges are built by diverse teams to develop new medical devices within successful medical device companies or divisions of larger corporations. Engineers are ideally suited to play leadership roles in this effort. Such entities succeed by combining strong visibility into the needs of their customers with access to talented technical, legal, and other experts and resources. Management of resources of this magnitude and complexity require major commercial entities.

After identifying the critical customers in the business model resulted from CVCA application, questionnaires were applied to all parties involved in order to survey and prioritize their requirements. The results from this study (primary source) were considered in association to others requirements from secondary sources, such as previous literature,

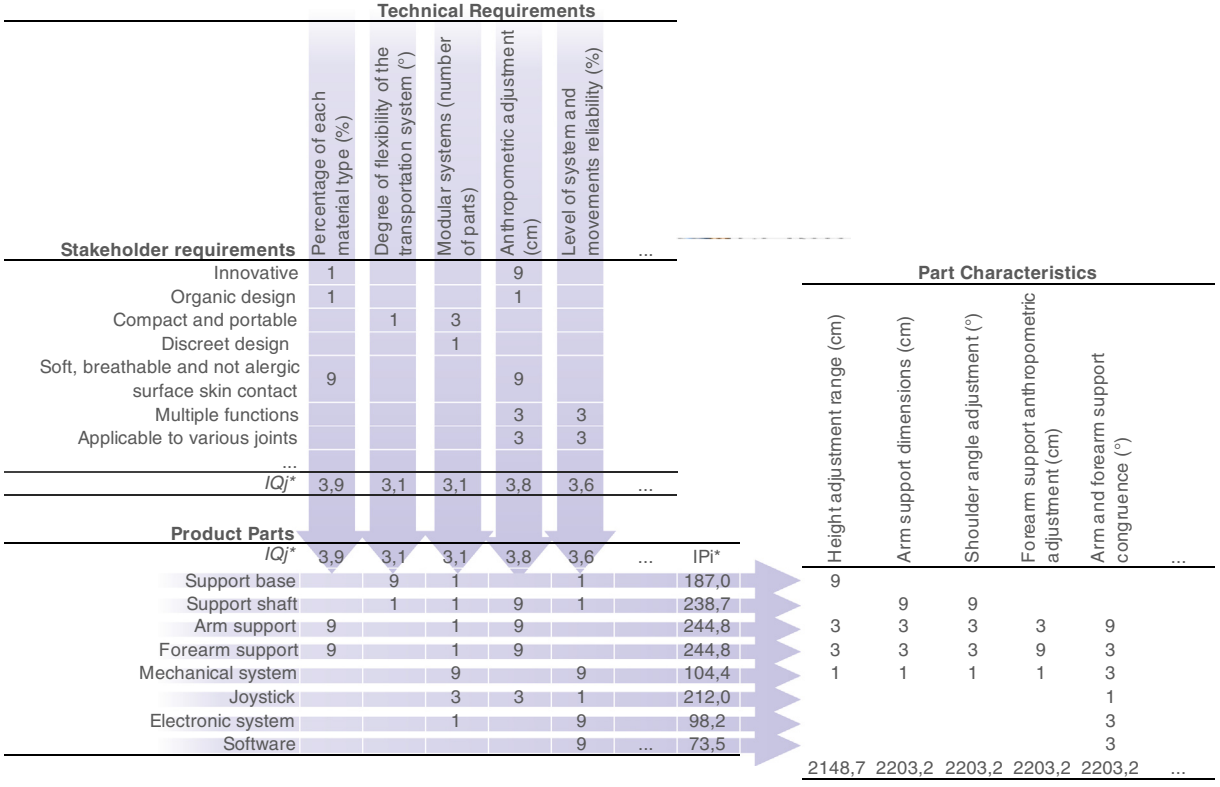

Fig. 4. Quality Function Deployment application.
Source: primary.

standards/legislation/regulators, and previous studies published by the research team. This novel approach of collecting stakeholders' requirements is more complete if compared to others which only consider what the literature reports about patients' and clinicians' needs (Bergmann and McGregor, 2011). Patients, clinicians, including care professionals (Saborowski and Kollak, 2015) are critical product life cycle stakeholders, but the perception of all those critical stakeholders identified by CVCA application should also be considered, analyzed, and prioritized. Our study approach is more systemic and integrated different important perceptions of whose make part of the medical device value chain.

Ana et al. (2013) emphasize a similar point of view, when they state it is becoming more prevalent for research teams to be multidisciplinary to take advantage of the diversity of skills and perspectives available within an organization. The research team can include ethnographic researchers, designers, human factor specialists, engineers, reimbursement specialists, marketers and sale managers. It is important to maintain a broad perspective and not limit the focus on too few stakeholders during the planning stage of a study. Potential solutions must be clearly defined and their value must be communicated to, understood, and mutually agreed upon by the multiple stakeholders who are involved in the life of the medical device. The initial approach of listening to the stakeholders or customers immediately posed the question: "who are the stakeholders?"

According to Kolominsky-Rabas et al. (2015) the diffusion of innovation in the health care market is subject to multiple requirements of third parties, including regulators such as the Food and Drug Administration (FDA) in the USA and European Medicines Agency (EMA) in the European Union. The National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária – ANVISA) is the regulator in Brazil. Previous studies developed by the research team showed that the association between the CVCA and QFD tools affected the customer definition and requirements elicitation phases in the development of a CPM device for elbow and forearm rehabilitation (Tanure et al., 2012a, 2012b).

Considering all of those previous results, this study presented a successful application of the CVCA tool associated with the QFD tool, describing the results in accordance with the engineering requirement process for the development of an innovative rehabilitation device for upper limb rehabilitation. It can be a new approach to manage requirements for medical devices development process. The elicitation step showed that most of the requirements identified in this study came from the critical stakeholders (CVCA application) and the majority of those identified by other methods (interviews and focused group) were repeated. Only two requirements were not identified by the critical stakeholders, but they were then highlighted by the graduate students of product development areas.

The analysis and documentation steps of the engineering requirements process showed that the primary customer requirements identified in the demanded quality survey (ergonomics, functions, aesthetics, handling, material, components/elements) were deployed in secondary customer requirements. These secondary customer requirements were transformed into product quality and technical requirements (quality characteristics, product parts and product part characteristics). Setting up the requirements is a step that starts at the beginning of the product development process and our study can help the medical devices development. The requirement list should still be continuously managed, amended and extended, depending on the state of the product design and the stage of the design process (Pahl et al., 2007).

6. Conclusions

The contribution of this study is the presentation of a novel approach using an association of CVCA with QFD tool to consider the different product value chain stakeholders to identify and prioritize requirements, product parts, and their characteristics managed by the engineering of requirements. The new model was applied in the development of a new elbow rehabilitation device. It makes clearer and more complete the process of discovering and identifying the critical stakeholders and their needs, as well as documenting these in a form that is amenable to analysis, communication, and subsequent implementation.

The identified and prioritized product quality and technical requirements should be considered in the development process of a novel medical device, as exemplified for the elbow rehabilitation device, which is the case of this study. Future studies should present the product development process steps. This model should also be used in the development process of other medical devices.

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Aline Marian Callegaro earned her PhD in Industrial Engineering (Quality Systems) from Federal University of Rio Grande do Sul, Master's Degree in Industrial Engineering (Production Management) and a Bachelor's Degree in Physical Therapy and Licensure in Special Graduation Program of Professors Formation to Professional Education from Federal University of Santa Maria.
Currently, she is an Adjunct Professor at North Coast Campus of Federal University of Rio Grande do Sul.
Her area of research includes Quality Systems; research line: Quality and Product and Process Development, Technological Innovation, and Ergonomics.

Carla Schwengber ten Caten earned her PhD's Degree in Material Engineering (1999), Master's Degree in Industrial Engineering (1995) and Bachelor's Degree in Civil Engineering (1992) from Federal University of Rio Grande do Sul and Bachelor's Degree in Physical Education (1989) from Methodist Institute of Porto Alegre (1989).
She is currently working as an Associate Professor II at Federal University of Rio Grande do Sul, Vice Director of Engineering College, Produto & Produção Journal editor and as a national and international Journals referee. She is also a Productivity Fellow PQ2 of CNPq.
Her areas of expertise include Quality Engineering. Themes: Quality Management and Control; Processes Statistics Control; Metrology, Design of Experiments (DOE); Product and Process Development and Optimization, and Technological Innovation.

Raffaela Leane Zenni Tanure earned her PhD in Industrial Engineering (Quality Systems) from Federal University of Rio Grande do Sul, and a Master's Degree in Design and Bachelor's Degree in Industrial Design – emphasis on Product Design; both from Federal University of Paraná.
Her area of research includes Quality Systems; research line: Product Development, Requirements Management, Usability and Value Dimensions of the Product.

Amanda Sória Buss earned her Master's Degree in Industrial Engineering from Federal University of Rio Grande do Sul and a Bachelor's Degree in Industrial Design, emphasis on Product Design, from Uniritter.
Her area of research includes Quality Systems; research line: Product Development, Packaging.

Márcia Elisa Soares Echeveste earned her PhD's degree, Master's Degree in Industrial Engineering, and Bachelor's Degree in Statistics from Federal University of Rio Grande do Sul, and Postdoc in Product Development from EESC-USP.
She is currently working as an Associate Professor at the Federal University of Rio Grande do Sul, acting in Undergraduate Program of Statistics and in Graduate Program of Industrial and Transport Engineering. She is also a Journals of Product and Production (ABEPRO) and Production (USP) referee.
Her area of expertise includes Industrial Engineering - Quality Engineering, acting on the following themes: Quality, Statistical Analysis, Statistical Quality Control, Product Development and Quantitative Research.

Carlos Fernando Jung earned his PhD in Industrial Engineering (Quality Systems) from Federal University of Rio Grande do Sul and a master's degree in Industrial Engineering (Product Design) from Federal University of Santa Maria.
He has been working as a Coordinator and Professor of Production Engineering since 2000 and Professor of Information Systems since 2001 at FACCAT. He is also a Coordinator and Researcher since 2001 at the Technology and Innovation Center of Paranhana/Encosta da Serra belonging to Technological Center's Program of the Department of Science, Innovation and Technological Development of State of Rio Grande do Sul, Brazil.
He has experience of 20 years (1980–2000) in Industrial Research and Development (R&D).

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