

REQUIREMENTS CAPTURE FOR MEDICAL DEVICE DESIGN

J Ward, S Shefelbine and P J Clarkson

Abstract

There are many examples from the medical device design industry where poor requirements capture practice has led to post-market problems, including patient morbidity and mortality. There is a clear need to improve this process. The purpose of this paper is to present the results of several years of study by five researchers into the requirements capture process in this area of industry and to highlight the need by industry for further guidance. Various research methods were used to investigate the requirements capture problem and to develop and evaluate a workbook which provides guidance for designers. The workbook consists of a package of methods: a functional analysis approach, a matrix-based checklist and advice on regulatory requirements. It has been refined over the years and is now published [1]. The matrix also forms part of a publication for the UK Department for Trade and Industry [2], and a web version is under development.

Keywords: best practice, introduction of methods, medical devices, requirements capture

1 Introduction

Medical device design involves the creation of healthcare products and the manufacturing and testing equipment used to produce them. It is a large and diverse industry, which often manufactures safety-critical products. Worryingly, however, device design-related problems can – and do regularly – cause serious difficulties for device patients and operators, ranging from near-misses to death. Since the mid 1990s, regulatory authorities world-wide have placed design controls on the design of medical devices and manufacturing equipment in order to identify such deficiencies before full production commences. Despite this, still all is not well in the medical device design industry.

Whilst design controls were being introduced, the Engineering Design Centre at the University of Cambridge, UK, began work to investigate current practice in medical device design, and to see why some of these design problems were occurring. Since gaining “good” requirements was identified consistently as a key area of difficulty for device designers, one of the areas of focus for this “Good Design Practice” research was that of requirements capture (defined here as the identification and documentation of the requirements that the device must satisfy).

The objectives of this research were to investigate current and good practice in this area; to develop guidance for designers on how to follow a ‘good’ requirements capture process; to evaluate this guidance; to refine it and finally to disseminate it to industry. This paper reports on the findings from this research. Observations in this paper are based on the work of several individuals, in particular Sandra Shefelbine [3]. Acknowledgements are given at the end of the paper.

2 Why do more research on requirements capture?

It is well established that requirements lay the foundation for the rest of the design, and that capturing them is therefore a very important process. Indeed, the Food and Drug Administration (FDA), which regulates medical devices in the US, states that gaining suitable requirements is the “single most important design control activity” [4]. Yet, capturing requirements can be a simple affair [4], partly due to the fact that comprehensive lists of recognised requirements are readily available, thanks to the existence of a multitude of general and device-specific standards.

However, many medical devices are complex and/or innovative. In such instances “it is not uncommon” for the design requirements definition stage to take as much as 30% of the total project time [4]. In addition, even for more simple devices, standards rarely go far enough to specify *all* the details for the device as they tend to allow room for at least some device innovation and diversity. All applicable standards must be considered (any failure to do so was described as a “fatal” error by a UK-based medical device consultant, interviewed by Ward in December 1998 [5]). Furthermore, as medical devices are usually safety-critical, there is a strong justification for paying particular attention to focusing on requirements; designers *have* to ensure that the requirements are right if the resulting design is to be fit for purpose. A further issue is that, similar to the design of many engineered products, high business pressures to minimise the time to market, development costs and product price, mean that any method to reduce these can be of significant benefit.

In practice, evidence abounds in the literature of problems related to requirements capture. For example, in software design Weinberg reports that up to 60% of errors originate with the requirements and analysis activities [6]. In the medical device industry, knowledge from potential users of the device is also under-utilised, suggesting that device firms may often fail to appreciate user needs. Further examples from the medical device field are given below:

“...the development of requirements for a medical device of even moderate complexity is a formidable, time-consuming task” [4]

“The thorniest issue in many companies is getting the technologists to truly understand the needs of the customer” [7]

“As currently practised, engineering lacks rigorous methods for capturing design requirements and verifying and validating the design itself” [8]

Given the nature of medical devices, the problems that occur and the lack of guidance, these observations suggest that there is a need for guidance on the requirements capture process for medical devices. Further evidence of this need will be discussed later in this paper.

3 Research methodology

Research began in 1997 with an investigation by Shefelbine [3] of requirements-related tools and literature and the regulations for medical devices in the EU and the US. Following from this, a workbook was developed, containing a method which presented ‘good practice’ guidance for medical device requirements capture. This workbook was then evaluated in an industrial setting. Supplemented by observations by Ward [5] and Alexander [9], further work by Ottavi [10], Farmer and Clarkson continued the development and evaluation of the workbook, culminating in a publication [1]. The research therefore followed an iterative pattern of investigation, development and evaluation, between several researchers.

3.1 Investigative research

Literature reviews and interviews with designers, both by Shefelbine and Ottavi, were used to investigate current thinking and practice in requirements capture. Together Ward and Alexander conducted a total of 38 interviews with device designers, and uncovered further examples of questionable practice [5, 9]. Shefelbine investigated this process further through discussions with designers and examination of documentation for a surgical device and an asthma inhaler under development.

3.2 Criteria for measuring the success of the method

During the investigative phase of the research, a general research aim was formed: to develop a method to help improve the fitness for purpose of a device, reduce the time to market, decrease the design costs, improve the communication of the requirements and increase confidence in the requirements. Based on the findings of this research, more measurable objectives were developed to help gauge the success of the method:

- Objective 1. *Output quality*: A successful method will generate ‘good’ requirements (defined later in this paper).
- Objective 2. *Process quality*: The requirements capture method itself should have other characteristics, such as usability, efficiency and effectiveness.

3.3 Development of a workbook

Following from the investigative work and the development of the success criteria, Shefelbine examined the requirements specifications of a pen injector and an asthma inhaler testing machine to develop a method for establishing device and manufacturing process design requirements. Interviews were also conducted by Shefelbine and Ottavi with device designers to further refine the description of the problem and to ask them what methods or tools would aid them in writing requirements specifications. Combining what was learned through these methods, a requirements capture workbook was developed over the course of two years.

3.4 Evaluation of the workbook

The workbook was evaluated in three ways. First, further interviews were conducted by Shefelbine, and later by Ottavi, by asking individuals to comment on the strengths, weaknesses and usefulness of the method.

Second, Shefelbine undertook three further case studies – a dialysis machine, a dialysis monitor and an infusion pump – taken from projects where requirements had already been developed for the device in question. With the researcher using the method, requirements were generated and then compared with the original lists. Gaps or inconsistencies were analysed, and the method was improved to address these problems.

Third, the method was evaluated by designers in a medical device company and its success was judged by comparing the results from the evaluative phase with the two objectives discussed above.

Informal evaluation was also obtained through a workshop; in general, results were very positive. Finally, the workbook will be evaluated by Ward through a series of workshops with designers in the medical device industry. Results from this broader phase of evaluation are awaited with interest.

4 Current practice in requirements capture

Shefelbine reviewed a wide selection of literature sources on requirements capture [3], which covered many requirements capture/management techniques such as checklists, Quality Function Deployment, co-operative requirements capture and various computer-based tools. Each had its strengths (such as structuring the requirements, determining trade-offs between them and facilitating their management), but in isolation from other methods was generally poor in aiding requirements *capture*; specifying that it must be done, but not how.

Further investigations into the requirements capture process were made by interviewing nine design engineers in a company which designed medical devices. Experience, checklists, previous specifications from similar products and brainstorming were the predominant requirements capture methods in use. More generally, some designers used story boards, flow charts, a simplified QFD-based method and block diagrams. However, it was found that none of the engineers used a standard method for capturing requirements, and that there was a desire to develop a method which combined some of these approaches into a single document.

4.1 Problems observed in requirements capture

Through the various research methods, the following difficulties were observed particularly frequently by Shefelbine:

- 1) *Conflicting requirements*. In requirements lists for devices, two or more requirements were often found that could not be met simultaneously.
- 2) *Missing requirements*. Although design reviews were found to be successful at identifying incomplete or incorrect requirements, there were frequent instances of a failure to identify all requirements in a timely manner.
- 3) *Incorrect requirements*. Such errors were often caused by communication difficulties between groups such as management, marketing and engineering. A failure to record the rationale behind the requirement was also seen as a contributing factor towards failing to identify incorrect requirements. Also, some of the requirements were simply “early guesses” which required updating, but were not identified as such, meaning that these might be forgotten about and be unwittingly used to dictate the final design.

For example, in the design of one device, three problems occurred: focus was made on the needs of the user to the detriment of the manufacturing and validation requirements, the full requirements specification was not written down until late in the project and the regulatory requirements changed during the project.

In the research by Ward [5], numerous examples were given of poor requirements practice. The most frequent complaints related to unclear requirements (particularly in the case of attempts to represent use conditions and the needs of users) and requirements which were not identified early in the design process and which arose later. This latter example was judged by one interviewee as being the “classic” problem. A typical response is given by one regulatory assurance manager:

“ [Requirements are] *my biggest gripe. Give me a proper specification! If you don't... how the hell do you expect me to prove whether or not the device works?* ”

Alexander also identified similar problems [9], including an example where designers had made an incorrect assumption regarding the use of the device, which was only identified during usability trials, late in the design process. The device had to be redesigned. From Alexander's 20 interviews with device designers/managers from six companies involved in

medical device design, nearly three quarters of the interviewees expressed a desire for further guidance on requirements capture.

More recent research by Clarkson and Ward *et al* [11] has also found many requirements-related problems in the industry. For example, medical device designers often fail to take into account the true range of user needs and the demands that are placed on the device by the lifecycle of its use. Many examples were given of device designs which have led to frustration at the difficulty of ease of use, inappropriate increases in training required and even harm to patients due to counter-intuitive or over-complex operation.

4.2 Possible causes of the requirements problems

Why were these problems occurring? The following observations, which suggest at least some of the causes, were made frequently in the research by Shefelbine and Ward:

- *Designers' attitude towards requirements capture.* The research results suggested that designers fail to realise the importance of good requirements capture. For example, Bishop states that designers see this process as “unrewarding” [12]. Riley concludes:
“ *the biggest error in the design input process is not putting enough time and effort into obtaining a complete and unambiguous list of requirements* ” [13]
- *Difficulty with capturing suitable data.* Another fundamental problem was that of the sheer difficulty of collecting suitable requirements. Ward, for instance, found this to be particularly difficult for some types of medical device design, such as those which require a precise understanding of conditions within the human body. When designing implanted devices, for example, an appreciation of the elasticity of human tissue may be required, yet such tissue can vary greatly according to age, type, collagen-elastin content and pathological state, and behaves in a highly non-linear fashion.

5 Good practice in requirements capture

The descriptive research identified a number of problems and possible causes. However, another aim of this was to investigate what might constitute good practice in requirements capture. This section presents the results.

5.1 Characteristics of ‘good’ requirements

A key question which required answering was: “what makes a ‘good’ requirement?” Research by Shefelbine concluded that ‘good’ requirements should be: *solution independent* (not specifying a solution to the problem), *complete* (e.g. capturing needs for all phases of the device lifecycle), *clear, concise, testable* (e.g. including quantitative limits) and *traceable* (traceable back to the rationale behind them and forwards to their implementation).

Research identified technical requirements, business requirements, and standards/regulatory requirements as three main classes of requirements that should be included for successful requirements capture. Shefelbine reviewed such regulatory requirements and device standards in the EU and the US, since these areas follow the vast majority of device regulations worldwide. Regulations state, for example, that requirements must be “appropriate” and must “address the intended use of the device, including the needs of the user and patient” [4]. Yet designers seemed surprisingly unaware of the details of such regulations.

5.2 Desired properties of the method

Other observations showed that a method should highlight the importance of starting requirements capture early in the design process. In addition, most designers were keen to have a simple and easily-used method which helps them to think about and explore the problem, rather than simply a checklist on its own.

6 Development of a new requirements capture method

Based on the above findings, it was concluded that the medical device industry would benefit from a new requirements capture method, which would help to identify and document requirements. The method should help the collection of ‘good’ requirements and aid the designer in problem understanding and in an appreciation of the regulatory requirements for medical device design.

6.1 An overview of the new method

The requirements capture method has three parts, different in their approach, which together help to ensure that a good requirements specification is drafted. These parts are: *functional analysis*, *requirements checklist* and *regulatory requirements guidelines*. The results from these parts are entered into a specification template, which aids the designer in organising and structuring the requirements specification document. The concept is illustrated in Figure 1.

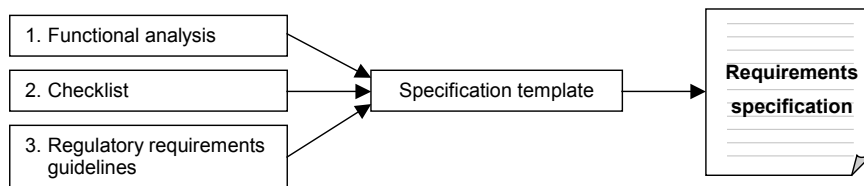


Figure 1. The requirements capture method.

6.2 Functional analysis

To help explore functional requirements, a FAST (Functional Analysis System Technique) diagram [14] was chosen by Shefelbine. For each sub-function, the question, “how is this to be met?” is asked. “How?” is answered by moving from left to right on the diagram; “why?” is answered by moving from right to left. The diagram is constructed by continuing to ask “how” for each function until the lowest level, elemental functions are established. As an example, a pen-type injector for medication delivery is considered in Figure 2.

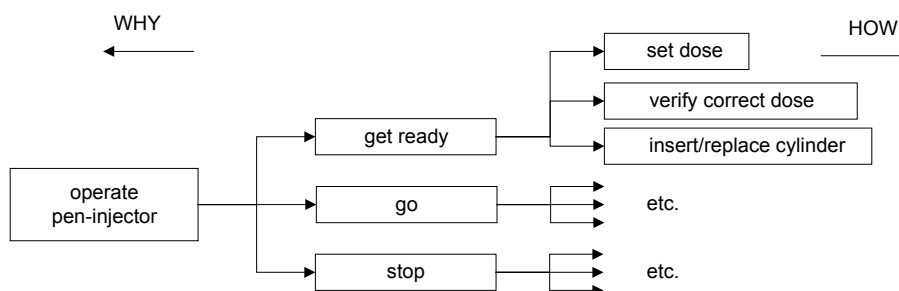


Figure 2. A (partial) FAST diagram, showing the decomposition of functions for a pen-injector.

During the research it became apparent that most devices must perform “get-ready”, “go” and “stop” functions [3]. These are also illustrated in this figure, and help to ensure that a comprehensive consideration of device functions is given by considering the lifecycle of use.

Extending the FAST diagram, the important functions may be expanded into separate *functional diagrams*, which identify the input parameters and the output response of each function. Consideration must also be given to how failures may occur with either of these. By forcing the designer to consider the answers to many questions, such diagrams can help requirements to be highlighted comprehensively. Once the diagrams are complete, “how” questions such as “how much,” “how many” and “how long” are considered, which help to derive performance requirements from the functional requirements. By analysing each function, requirements are then organised into a requirements specification document.

6.3 Requirements checklist

The research methods identified a multitude of different types of requirements, yet most of the requirements highlighted through the functional analysis apply to a particular function, not to the product as a whole. Consequently, extensive efforts were directed towards producing a requirements checklist which helps identify further types of requirements. In addition to conducting case studies and interviews, an expansive range of literature sources was consulted from various industries, including academic, regulatory and industry books, journals and standards. The resulting checklist was presented as a matrix where, originally, the (six) rows traced the life cycle of the product, from design to disposal, and the (nine) columns addressed the general requirement areas. Each of the 54 cells in the matrix contained a separate list of requirements which were specific to that part of the lifecycle and general requirement area. Thus, a very large number of potential requirements was presented.

After gaining feedback on the matrix (see Section 7 for details), further work was conducted by Shefelbine, and later Ottavi and Farmer, to simplify the method and improve its usability. Following Shefelbine’s modifications, the matrix was broken down into its component parts by Ottavi. To gain further ideas about how to rearrange it in a logical fashion, a further literature review helped to identify additional requirements and to present ideas as to how to re-phrase the names of the cells within the matrix into a clearer language. Through consultations with the designers, and work with Farmer and Clarkson, Ottavi redefined the cells, reduced their number by removing some elements and adding others, and restructured the matrix. To improve the usability of the matrix its cells were also rearranged so that its top left hand area incorporated the most important requirements. The reformatted matrix was reduced to 35 cells and is shown in figure 3.

In addition, Ottavi incorporated the matrix into a computer tool. This allowed easier navigation through the matrix and comments for each requirement to be added, where so desired. Further work is underway to create a web version of the matrix.

6.4 Regulatory guidance

Shefelbine found that interviews with designers revealed “an acute lack of knowledge about, and near fear of, regulatory requirements” [3]. This was characterised by a severe lack of understanding of device regulations. Although much guidance was provided by institutions such as the FDA, designers still wished to be taken gently through the “minefield of information.” In recognition of the excellent guidance which already exists, the regulatory guidance section in the workbook summarises the key requirements, but directs designers to the relevant source if further information is required.

6.5 Requirements specification template

Through using the functional analysis and matrix checklist, many requirements may be generated, but they are not yet arranged in an orderly fashion. A template was presented as a suggested format for the requirements specification document, based on observations of specifications from medical device projects in industry. This supplied the main heading and possible sub-headings of the requirements specification. The requirements generated from each of the three parts are manually entered into the specification and designers are prompted to consider the characteristics of ‘good’ requirements when drafting the specification.

		Process	Performance	Safety	Cost	Documentation
Product in Use	Operation	Operation Process	Operation Performance	Operation Safety	Operation Cost	Operation Documentation
	Maintenance	Maintenance Process	Maintenance Performance	Maintenance Safety	Maintenance Cost	Maintenance Documentation
	Disposal	Disposal Process	Disposal Performance	Disposal Safety	Disposal Cost	Disposal Documentation
Product Design / Manufacture / Supply	Design	Design Process	Design Performance	Design Safety	Design Cost	Design Documentation
	Manufacture	Manufacturing Process	Manufacturing Performance	Manufacturing Safety	Manufacturing Cost	Manufacturing Documentation
	Distribution	Distribution Process	Distribution Performance	Distribution Safety	Distribution Cost	Distribution Documentation
	Installation	Installation Process	Installation Performance	Installation Safety	Installation Cost	Installation Documentation

Types of Use

- intended use
- special use
- non-use (storage)
- misuse (abuse)

Modes of Use

- etc...

Manpower

- Internal staff
- subcontract staff
- design consultants

Materials

- cost of prototyping materials
- etc...

Figure 3. The finalised matrix checklist, showing some of the specific requirements for two categories.

7 Evaluation of the requirements capture method

During Shefelbine’s interviews to evaluate the method, comments were generally very positive. Although there was some resistance to the functional analysis, which was seen as a somewhat restrictive, designers generally felt the approach to be beneficial, given the safety-critical nature of medical device design. Shefelbine also evaluated the method by comparing requirements generated in a normal fashion by an engineer experienced in the writing of requirements, and those generated by a novice engineer who followed the method.

The specifications were compared to identify the effects of the method on requirements capture. The senior designer generated 46 requirements; the junior, 73. Perhaps more importantly, however, one of the key differences between the requirements produced was in their quality. By examining the requirements generated by the junior engineer, and comparing them with the desirable characteristics of ‘good’ requirements, they were found to have a higher “output quality”. For example, many “to be decided” requirements were generated by both designers. However, the senior designer failed to identify *what* was to be decided,

whereas the junior designer stated requirements much more specifically, which helped testability. Shefelbine concluded that the “process quality” was also good, as the method produced a formatted requirements document, containing ‘good’ requirements and that a novice designer was able to use the method successfully.

In further evaluation by Shefelbine, the dialysis machine, dialysis monitor and infusion pump case studies revealed a number of opportunities for improvement. The need was highlighted for a step-by-step approach as it was difficult to know when to use each part of the method. In addition, the method required a “specific modes of use” category and a category for requirements in the event of a device failure. Consequently, Shefelbine modified the method.

Ottavi took over the research, and evaluated the modified approach again with engineers in the medical device industry. Although Shefelbine concluded that the method had met both objectives, these designers found it unwieldy and daunting due to the high number of cells. Nearly half of the elements were judged by the designers to be either unclear or poorly-placed and some important issues were still missing. Moreover, there was a need to take into account some other aspects of the design such as risk management and environmental conservation. In addition, the definitions of some of the cells were found to be unclear.

After further modifications by Ottavi the ‘finished’ matrix was met with an enthusiastic response from designers as it was felt to be much more manageable. In addition to a positive verbal response, numerical evaluation showed that designers found nearly 90% of the elements to be clearly defined and in the correct place.

Further evaluation of the workbook will take place through presentations and discussions with a wider set of companies. It is hoped that this will increase the industrial uptake of the workbook, and provide further feedback from ‘real-life’ situations.

8 Conclusions

Effective requirements capture is a prerequisite to successful medical device development. However, investigations by several researchers showed consistently that further guidance was needed for following a successful approach. Consequently, a requirements capture method was developed, which is now published in the form of a workbook [1]. Through various courses of evaluation and extensive modification, the finished workbook consists of three key parts: a functional analysis method, which helps to produce both functional and performance requirements; a checklist matrix, which helps to capture general requirements for the device; and regulatory guidelines, which highlight key regulatory considerations.

The method was found to be successful as it generated requirements with the desired characteristics such as completeness, clarity, and solution independence, and led designers through a process that aided them in establishing the requirements. Using the method, a novice designer was able to develop a requirements specification which was more comprehensive, organised and structured than that which was produced by an experienced engineer. Further evaluation of the workbook in an industrial setting will take place during the next stages of the “Good Design Practice” research at the Engineering Design Centre.

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James Ward
Engineering Design Centre
University of Cambridge
Trumpington Street
Cambridge CB2 1PZ
United Kingdom
Tel. Int +44 1223 766 957
Fax. Int +44 1223 766 963
E-mail: jrw38@eng.cam.ac.uk
URL: <http://www-edc.eng.cam.ac.uk/people/jrw38.html>