

# Optimising the Development of a Medical Device Using Formal Engineering Design Techniques and the CODA-System

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## Abstract

This paper summarises work that has been carried out to date on the UK government funded (MedLINK) research project 'SuPort'. The project is concerned with the development of an innovative urine drainage system, which is designed to treat patients who have dysfunctional bladder problems.

The development of this novel device has presented a number of severe design challenges in order to find feasible alternative design solutions, requiring expertise from a range of disciplines including urology, materials science, hydrodynamics, ergonomics, aesthetics, surface mechanics, microbiology, surgery, nursing, manufacturing, structural design and mechanisms. The design space for this device is highly constrained in terms of the limited range of certified biocompatible materials that possess suitable engineering characteristics for use in this application. This paper identifies how a multi-disciplinary team solved these problems achieved using a range of formal design methods.

The paper reports on the strengths and weaknesses of these formal design methodologies and suggests enhancements. In particular, the paper shows how a diverse range of methodologies can be integrated and suggests specific enhancements to QFD, termed the CODA-System. This system enhances the QFD method to allow alternative designs to be compared in an objective way using a dimensionless merit factor. This merit factor is generated from the part attributes and terms how closely they meet the individual idealised targets. This approach addresses the widely acknowledged shortcoming of QFD namely the specific nature of a QFD matrix. The dimensionless merit factor allows a wide variety of design configurations to be evaluated using the depth of a QFD matrix but gives the generality of concept evaluation methodologies.

## Keywords

Quality Functional Deployment, Design Optimisation, Customer Optimised Design Analysis

## 1 Introduction

### 1.1 The Clinical Problem and the SuPort Project

Apart from materials, the suprapubic Foley self-retaining balloon catheter has not significantly changed since it was first designed over 50 years ago. Suprapubic long-term catheterisation (LTC) is considered by the medical profession to be used only as a last resort for those with loss of bladder control. LTC is associated with serious complications such as catheter blockage, the catheter drainage 'eye' embedding in the wall of the bladder, encrustation and stone formation.

The SuPort project is a 4 year, UK government funded MedLINK project which involves the collaboration of industrialists, urologists and academics in the form of 4 partners: SSL International, KeyMed (Medical and Industrial Equipment Ltd), North Bristol NHS Trust, and the University of the West of England, Bristol. The initial design brief underlined the main objectives of the project as the design and development of 3 medical devices aimed at targeting the clinical problems associated with suprapubic LTC. A self-retaining suprapubic port that replaced the balloon retention-mechanism was the *primary medical device*, which would also provide permanent access to the bladder and accommodate 2 other auxiliary devices designed to be used with the port.

## 2 DESIGN THROUGH SELECTION: Project Planning - Identifying an Appropriate Design Process to Achieve Current Good Design Practice (cGDP)

### 2.1 Achieving cGDP

It is essential that medical devices are developed in line with current Good Design Practice. Highlighted in [Alexander and Clarkson 1997, 1999a, 1999b], is that medical device design differs from conventional design as extensive regulations from the European Medical Device Directives (MDD) and the Federal Drug Agency (FDA) require that validation and design procedures are in place throughout the design phase. Here it is indicated that there is general confusion regarding validation (*have we built the right thing*) and verification (*are we building the thing right*) within the medical device industry. And the industry must consider how design and validation activities are understood in order to produce effective products resulting from good design practice.

In terms of project planning, our problem was to determine which design techniques should be utilised in order to avoid confusion within the multi-disciplinary team. This needed to be achieved without compromising time and design optimisation while conforming to cGDP.

### 2.2 Identifying an Appropriate Design Process

There are many techniques and methodologies within engineering design literature that have been developed in order to select designs, using multiple criteria or attributes, to rate a number of alternatives for further design synthesis. An evaluation of practical applications using various systematic engineering design techniques is presented in [De Boer, 1989]. An established method of concept generation, initially presented by [Pugh 1981] to produce primary designs for selection, is presented by [Kuppuraji, 1985] in a selection-decision support problem (selection-DSP). This is a 2-phase design approach: Phase-1 recognition of need, generation of concepts and preliminary selection of feasible alternatives. Phase-2 deals with the identification and ranking of attributes, evaluation of alternatives (based on multiple attributes), ranking of alternatives and post solution analysis. An enhanced method of formulating selection-DSPs using quality functional deployment (QFD) as an auxiliary technique to identify attributes is presented in [Bascaren, 1991]. For brevity, the adaptation and expansion of the approach in [Kuppuraji, 1985] and the QFD approach furthered in [Bascaren, 1991], used in the practical development of the SuPort device is presented in section 3. A more detailed presentation can be found in [Woolley et al 2000].

## 3 The 2-Phase Design Process Used In The Development of a Medical Device

### 3.1 Phase-1(sub-phases 1.1-1.2)

Illustrated in Figure 1 are the chosen design techniques in the phase-1 design process utilised to generate feasible design alternatives to be used as inputs for optimal selection and post solution analysis. Figure 2 illustrates a selection of the bladder retention design alternatives used as inputs to the phase-2 selection process. Prior to the phase-2 selection-DSP, the design alternatives were validated with respect to a bench marked bladder retention force, as these concepts were functionally unproved and the crux of the design.

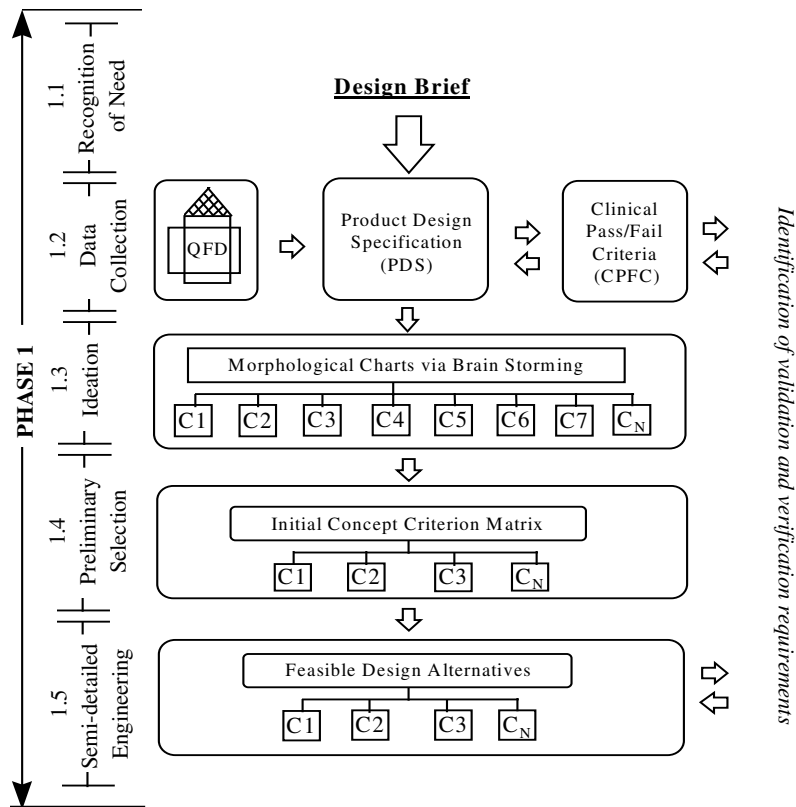


Figure 1: Schematic structure illustrating techniques used in phase 1

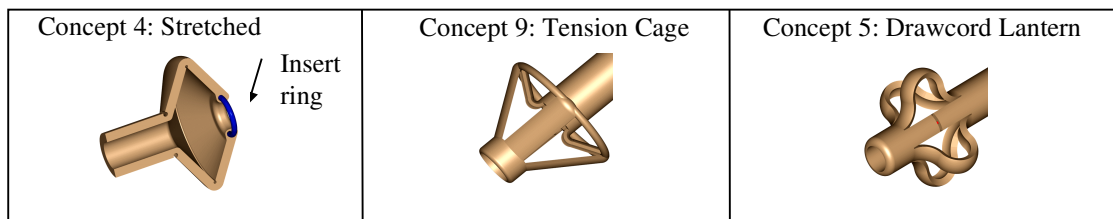


Figure 2: Sample of bladder retention-mechanism feasible design concepts used as inputs to the (sub-phase 2.1) selection-DSP

### 3.2 Phase-2 (sub-phases 2.1- 2.2)

To summarise, what follows is a step-by-step presentation of the formal design techniques (Figure 3) as presented by [Woolley et al 2000] and used by the SuPort multi-disciplinary team in the selection of a superior design alternative.

- Step 1: Use QFD 'house of quality' matrix to identify and rank additional design attributes ( $j$ )
- Step 2: Determine normalised relative importance of attributes ( $I_j$ )
- Step 3: Rate alternatives and normalise attributes ( $R_{ij}$ ) with the aid of selection charts
- Step 4: Solve the selection-DSP and determine MAX ( $MF_i$ )
- Step 5: Post solution sensitivity analysis
- Step 6: Final detailed design analysis

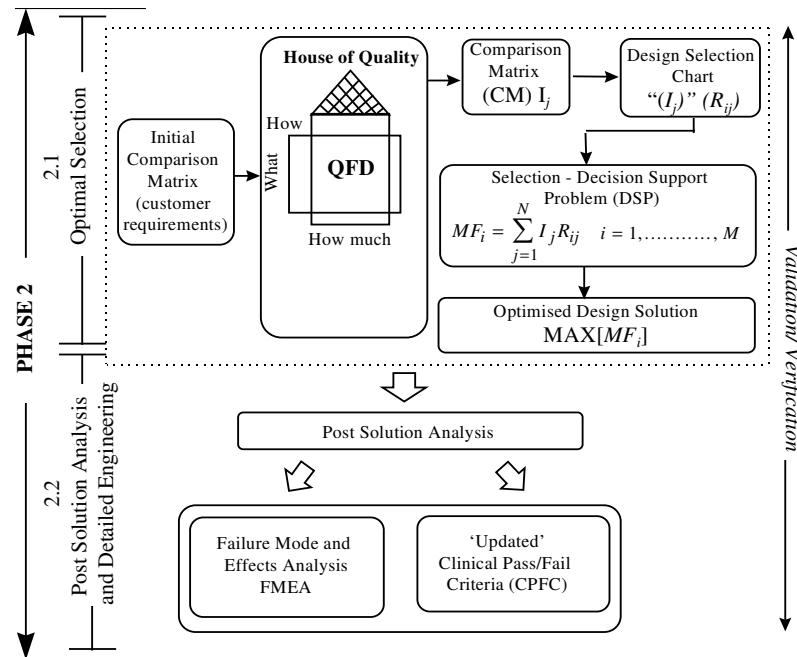


Figure 3: Schematic structure illustrating techniques used in phase 2

## 4 Optimising Design using the CODA-System

### 4.1 QFD Enhancements

The improved QFD approach presented by [Basaran, 1991], used in phase-2 of the design method, determined a superior design solution from a number of alternatives, utilising a set of ranked customer requirements and design attributes identified in the phase-2 QFD matrix. Further improvements to QFD are presented in [Clausing and Andrade, 1996], where they introduce the enhanced quality functional deployment approach (EQFD) which integrates the concept selection matrix [Pugh, 1981] into the basic deployment steps. A summary of the state of the art and future directions of QFD is offered in [Sivaloganathan and Evbuomwan, 1997].

It is well known that the initial QFD matrix holds valuable amounts of information but, to analyse this information in order to determine superior designs is difficult and time consuming, especially when using a multi-disciplinary team. Although integrating QFD into 'user friendly' software is the general consensus, we have found that research into using the information already available in the initial matrix is limited.

Taguchi's quality loss function (QLF) [Belavendram, 1995 and others], indicates how customer requirements can be used to determine quantitative design parameters using three types of targets: nominal-the-best, smaller-the-better and larger-the-better. We believe that integrating the QLF approach with the information held within the initial QFD matrix, is the next evolutionary step in the QFD method. We have termed this step the Customer Optimised Design Analysis-System (CODA-System).

### 4.2 The CODA-System

The CODA technique deals with the disunity imposed on a candidate design solution by a set of conflicting customer requirements. The technique assumes that an ideal design solution is obtained when each customer and technical requirement achieves its designated *perfect* value. In such circumstances the CODA system yields an overall merit factor (MF) that indicates the performance of a design in percentage value terms. The system makes use of an initial QFD matrix, which arranges the customer requirements in rows and the technical requirements in columns across the top of the matrix in the standard format. The relative customer importance is then normalised and listed next to the corresponding customer requirement. As with the initial

QFD matrix, the CODA matrix also makes use of the correlation between each customer requirement and each design parameter. However, in this case the CODA technique makes use of the following ordinal (0–1) scale where (1) represents a very strong correlation. The underlying principle of the CODA-System is that it addresses the conflicts between each customer requirement and each technical parameter in isolation (*ignoring other customer and technical requirements*). The technique deals with the notion of obtaining an *ideal* design by introducing Maximise, Minimise and Optimise equations, with which a different merit value (mv) for each design parameter can be calculated, depending on one of the 3 relationships.

#### 4.3 Relationship 1: ‘The bigger the better’ – Maximise mv

$$Max_{mv} = 1 - e^{(-AP/LTP)} \quad \text{Equation (1)}$$

Where: LTP = Local Target Parameter (*derived by each individual customer requirement*)

AP = Actual Parameter

Figure 4 illustrates the maximise merit function presented in (1). In this example the LTP is 4, hence ‘the bigger’ AP becomes ‘the better’ or the higher the merit value obtained and the greater the customer satisfaction. However, when LTP and AP are equal the customer is deemed to be satisfied. This satisfaction point is expressed mathematically as ‘ $\beta$ ’. Where  $\beta$  indicates the lower limit of the ‘Customer Satisfaction Point’ (CSP). Thus, at mv’s below this point the customer is considered to be dissatisfied.

When LTP = AP

$$mv = 1 - \frac{1}{e} = \beta$$

$$\beta \approx 63\%$$

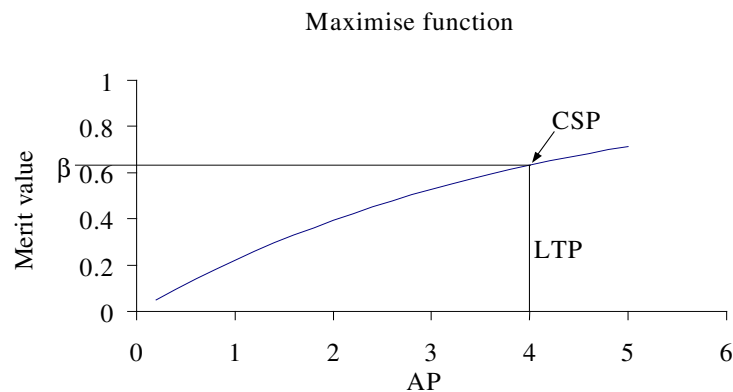


Figure 4: Graph of  $Max_{mv}$

#### 4.4 Relationship 2: ‘The smaller the better’ – Minimise mv

$$Min_{mv} = 1 - e^{-(LTP/AP)} \quad \text{Equation (2)}$$

Figure 5 illustrates the minimise merit function presented in (2). Let LPT remain at a value of 4, hence ‘the smaller’ AP becomes ‘the better’ or the higher the merit value obtained and the greater the customer satisfaction. Similarly, when LTP and AP are equal the customer is deemed to be ‘ $\beta$ ’ satisfied. In this case  $\beta$  indicates the upper limit of the ‘Customer Satisfaction Point’. Thus, at mv’s above this point the customer is judged to be dissatisfied.

When  $LTP = AP$

$$mv = 1 - \frac{1}{e} = \beta$$

$$\beta \approx 63\%$$

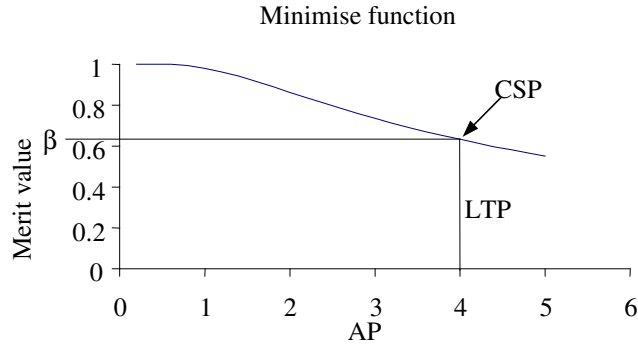


Figure 5: Graph of  $Min_{mv}$

#### 4.5 Relationship 3: ‘Converge to local target parameter’ – Optimise mv

Converge to Local target parameter’)  $Opt_{mv} = e^{-\left(\left(\frac{(LTP-AP)}{Tol}\right)^2 \cdot \ln \beta\right)}$  Equation (3)

Where:  $\beta$  = Merit value at the Customer Satisfaction Point (CSP)

Tol = Distance between LTP and AP when  $\beta \approx 63\%$

$Opt_{mv}$  is a scaled normal distribution with a maximum value of 1 so that it is consistent with  $Max_{mv}$  and  $Min_{mv}$ . Again  $\beta$  indicates the ‘Customer Satisfaction Point’ where mv’s to the left of the Lower-CSP and to the right of the Upper-CSP are deemed to be dissatisfactory by the customer. Utilising the same value for LTP and (3) it can be seen (Figure 6) that as AP increases towards the LTP, the higher the mv obtained and the greater the customer satisfaction. Figure 6 also illustrates the Lower (LC) and Upper (UC) constraints, determined through expert engineering judgement, utilised to calculate the overall MF.

When  $LTP + Tol$  and  $LTP - Tol = mv$ ,

$mv = \beta$ , where  $\beta \approx 63\%$

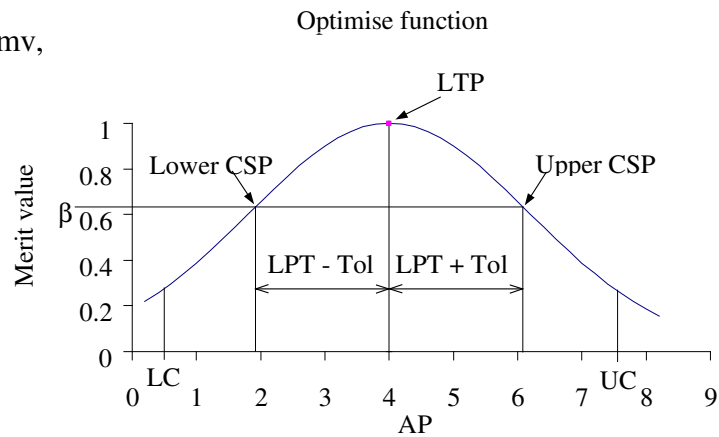


Figure 6: Graph of  $Opt_{mv}$

Equation (4) calculates the overall merit function (MF) for the particular design once all conflicts (merit values), correlations and customer importance have been identified and analysed.

$$MF = \sum_{a=1}^m \left( \frac{\sum_{b=1}^n (cor a_m b_n \times mv a_m b_n)}{\sum_{b=1}^n cor a_m b_n} \right) \quad \text{Equation (4)}$$

Where: a = Normalised customer importance (0-1)

b = Technical requirements (target parameters)

cor = Correlation value (0, 0.25, 0.5, 0.75 or 1) where 1 is a perfect correlation

#### 4.6 The CODA-System: Design Optimisation and Selection

The expressions and technique within the CODA matrix can be formulated into a spreadsheet model in order to assist the user by simplifying the process with the aid of software. The CODA matrix design optimisation model illustrated in Figure 7 is a 4x3 matrix, using a sample of requirements originally used in the phase-2 Selection-DSP discussed in section 3. Customer requirements and their normalised relative importance (a<sub>1</sub> to a<sub>4</sub>) are represented as rows and the corresponding technical parameters (b<sub>1</sub> to b<sub>3</sub>) as columns.

		b <sub>1</sub>					b <sub>2</sub>					b <sub>3</sub>					Customer Satisfaction
		Retention force of mechanism (N)					Tube I.D. (mm)					Tube Hardness (Shore A)					
Normalised customer importance		Correlation	Local target parameter	Relationship type	Tolerance (for type opt)	Merit value (mv)	Correlation	Local target parameter	Relationship type	Tolerance (for type opt)	Merit value (mv)	Correlation	Local target parameter	Relationship type	Tolerance (for type opt)	Merit value (mv)	
a <sub>1</sub>	Quick to empty	0.40		MAX ▼			1.00	4.0	MAX ▼		0.59			MAX ▼			0.23
a <sub>2</sub>	Safe to use	0.10		OPT ▼			0.25	3.5	OPT ▼	0.25	0.99			MAX ▼			0.10
a <sub>3</sub>	Comfortable	0.30	0.50	12.0	MIN ▼	0.63	0.75	2.0	MIN ▼		0.43	1.00	60.0	MIN ▼		0.55	0.16
a <sub>4</sub>	Reliable	0.20	1.00	30.0	MAX ▼	0.33	1.00	4.0	MAX ▼		0.59	0.25	70.0	OPT ▼	30.0	0.99	0.10
Actual parameter		<b>12.00</b>					<b>3.53</b>					<b>75.00</b>					<b>59.60%</b>
Constraints (U, L)		30.00					6.00					120.00					
		12.00					2.00					75.00					<i>Merit Factor</i>

Figure 7: Example of CODA-Matrix Design Optimisation Model

For example, taking cell (a<sub>4</sub>, b<sub>1</sub>) in isolation, an appropriate correlation between the customer and technical requirement is chosen. Here, the LTP has been judged to be a force of 30N but, the customer would prefer this to be 'bigger the better' and therefore has chosen the Max<sub>mv</sub> relationship. However, cell (a<sub>4</sub>, b<sub>1</sub>) and cell (a<sub>3</sub>, b<sub>1</sub>) are in direct conflict, as customer requirement (a<sub>3</sub>) would prefer the force to be 'smaller the better', and therefore has chosen a LTP of 12N and consequently a Min<sub>mv</sub> relationship. In essence, the process of dealing with conflicts in this way eliminates the requirement for the 'roof' of the matrix. The operation of dealing with each customer requirement and each technical parameter is repeated until all cells within the matrix have been analysed. Equation (4) then calculates the overall optimised MF by varying the AP value, with in the spreadsheet, subject to the constraints.

The example pictured in Figure 7, illustrates how easily information contained within the matrix can be interpreted. In particular, the model allows the user to instantly view the overall performance (MF) for the specific design under analysis. It also enables one to determine which relationship type and corresponding mv's are influencing the design's overall achievement.

#### 4.7 Conclusions and future work

Presented is a summary of the research and development undertaken within the SuPort project by a multi-disciplinary team towards the practical design and development of a medical device. The techniques utilised in phase-1 of the design process, in particular the product design specification, focused the team and ensured that essential design information was not overlooked when generating initial concept solutions. Selection-DSP's used in phase-2 of the design process ensured that a superior design alternative was selected for further development. One can also conclude that the use of formal design techniques within medical device development ensures the best designs are attainable while adhering to cGDP.

Also presented is the CODA-System for use in design optimisation and selection. It seems clear to us that this technique is the next evolutionary step in the QFD approach. The general consensus from the multi-disciplinary team is, compared to selection-DSP's, the CODA-System is easier to comprehend, less time consuming and user friendly. The use of the 'roof' in the house of quality QFD matrix is eliminated as conflicts are addressed, in isolation, within the matrix. Although the technique is still in its early stages of development, it is clear that this method could eventually replace selection-DSP's within phase-2 of the design process.

Further research on the CODA-System is currently being undertaken at the University of the West of England, Bristol, UK. This research involves sensitivity analysis, the use of skew distribution functions in the optimise equation, integrating the system with other techniques and testing the system using the practical research and development of medical devices.

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