

your companion on

Robust Design

- an industry guide for medico and pharma -



Design is not
just what it
looks like
and feels
like. Design
is **how** it
works.

Steve Jobs / 1955-2011

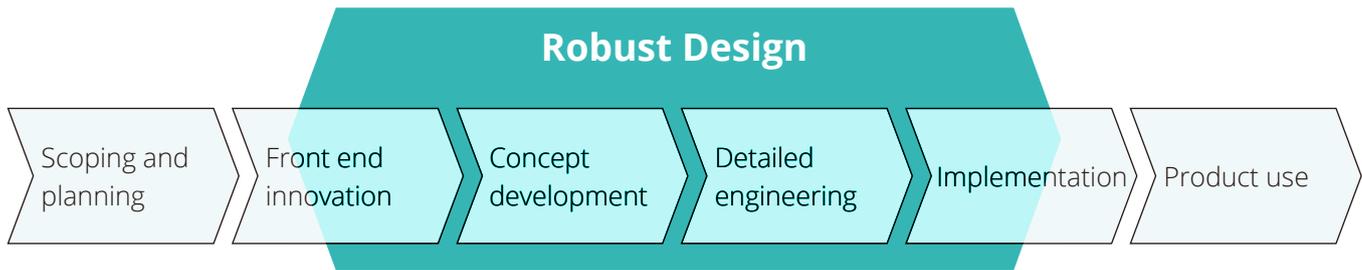
The core principle

The objective of Robust Design is to minimize the sensitivity of a product towards variation factors encountered throughout the life cycle of the product. This is explained by the core principle of Robust Design, explained in three steps.

STEP #1

WHEN | APPLYING ROBUST DESIGN

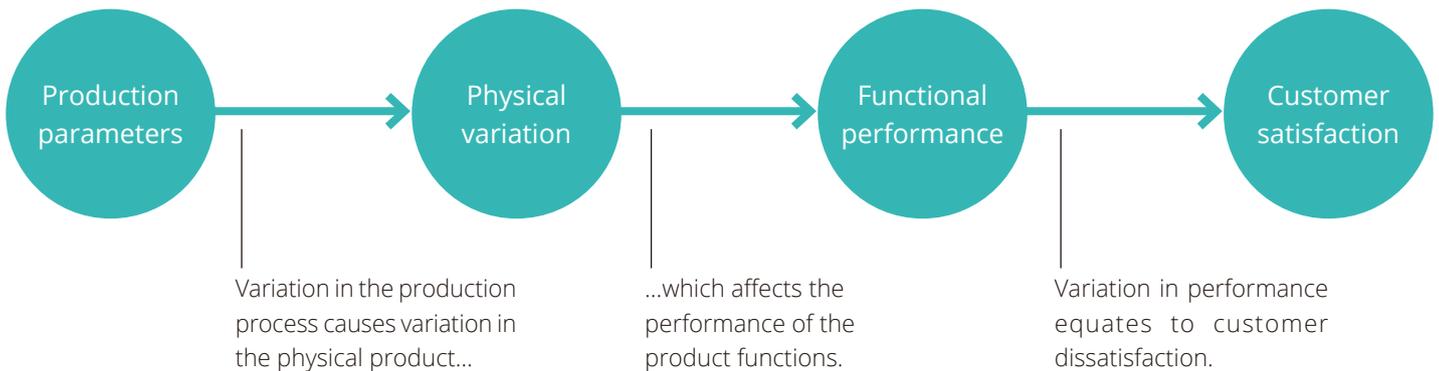
Robust Design is all about creating products with low sensitivity to variation. Strict production control is costly, but applying Robust Design methodologies during the R&D phase reduces the necessity of tight tolerances.



STEP #2

WHY | CUSTOMER SATISFACTION

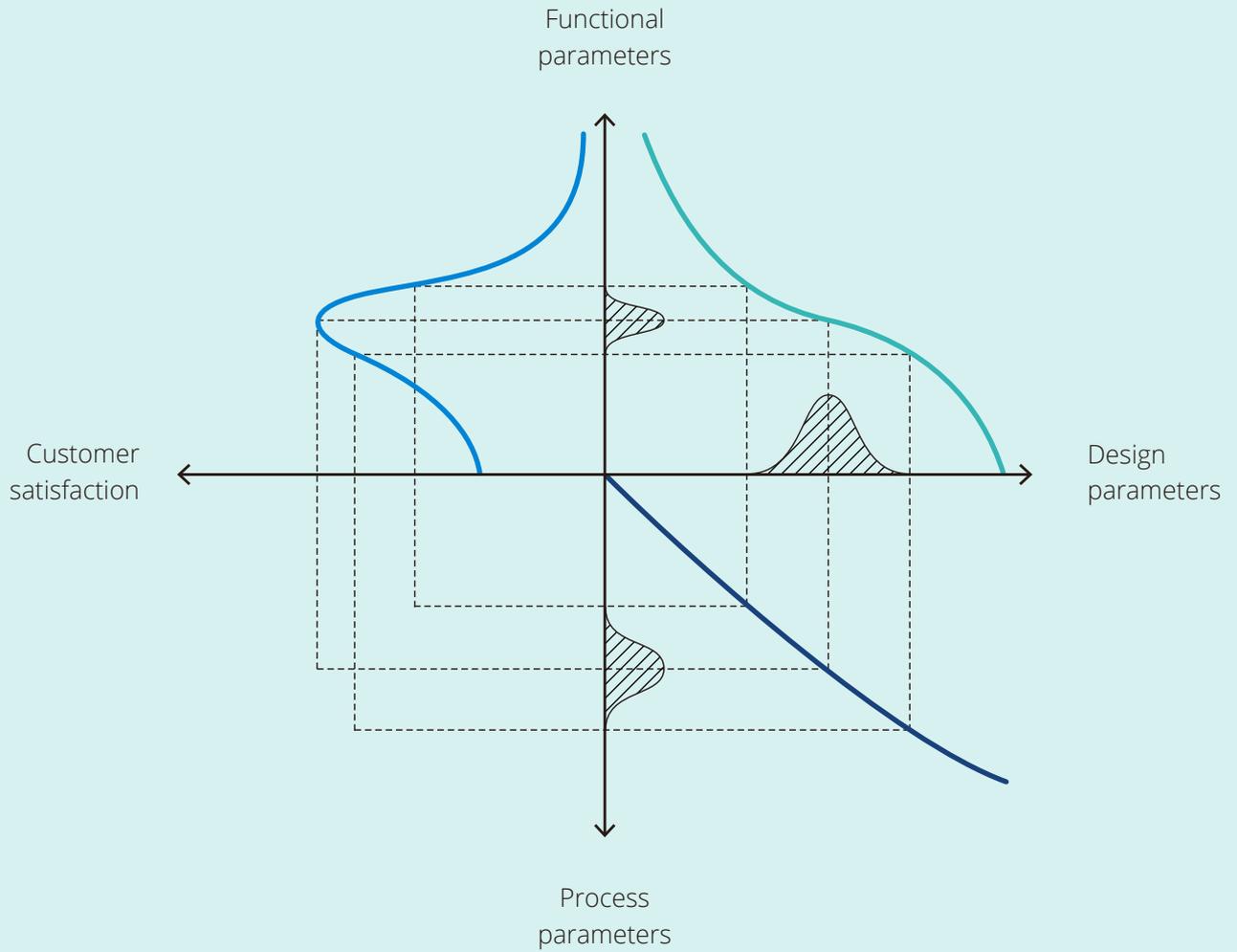
When dealing with Robust Design, the road to customer satisfaction links production parameters to quality loss through physical – and hence functional performance variation. If the design is more insensitive to physical variation, not only the end-user satisfaction increases, but also the internal costs associated with e.g. scrapping and concept reworking are minimized.



STEP #3

HOW | PARAMETER IMPACT

The variation from one domain (the axes in illustration 03) is transferred to another through a transfer function. Robust products have a low degree transfer of variation of physical parameters to functional performance.



- Quality Loss Function
- Flat Transfer Function, implying low variation transfer, i.e., a Robust Design
- Transfer Function derived from traditional Six Sigma efforts

ILLUSTRATION 03 | Visualizing the cause and effect (Howard, 2014)

The seven methods

These seven tools and techniques you can use in your daily work as a mechanical engineer, when aiming for a Robust Design.

METHOD #1

KINEMATIC ANALYSIS

Kinematic analysis is utilized to ensure the intended mobility of a mechanism or a static construction. If too many degrees of freedom are constrained the construction is over-constrained and thus more sensitive to variation.

Kinematic analysis is used to achieve a less complex tolerance chain and avoid jamming in mechanisms. The mobility of a structure can be assessed using the Kutzbach criterion:

$$M_{2D} = 3(n_{\text{links}} - 1) - n_{\text{constrained DOFs}}$$



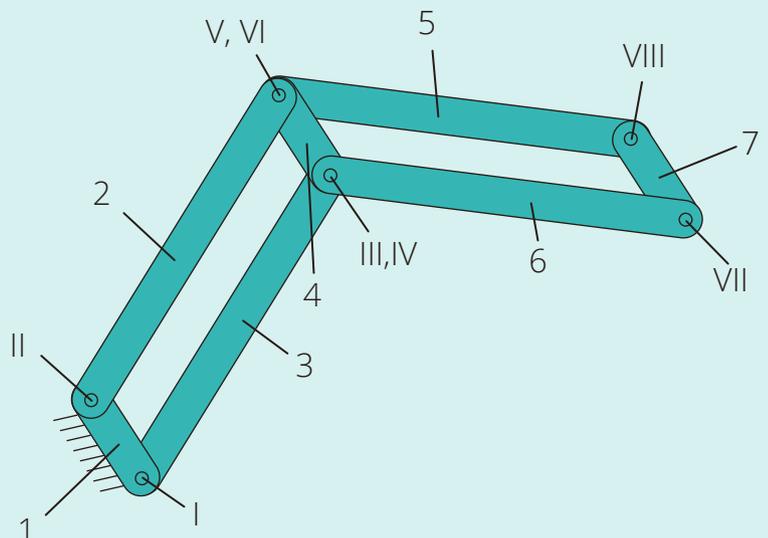
EXAMPLE | The architects lamp; a 7-link mechanism

$$n_{\text{links}} = 7$$

$$n_{\text{constrained DOFs}} = 2 \times 8$$

$$M_{2D} = 3(7-1) - 16 = 2$$

Thus the mechanism requires two actuators to be fully defined. Or the removal of two degrees of freedom i.e. friction in two joints.



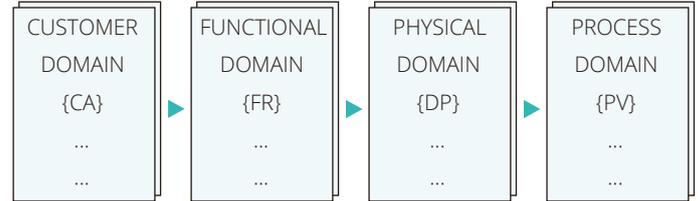
METHOD #2

AXIOMATIC DESIGN ANALYSIS

Axiomatic design analysis finds its use when analysing how coupled a design is. If many design parameters (DP) influence the same functional requirement (FR), a design is coupled. Alternatively, if a single DP influences multiple FR's, a design is also coupled.

Axiomatic design analysis is used to reduce the coupling degree of the system in order to reduce the amount of variation sources.

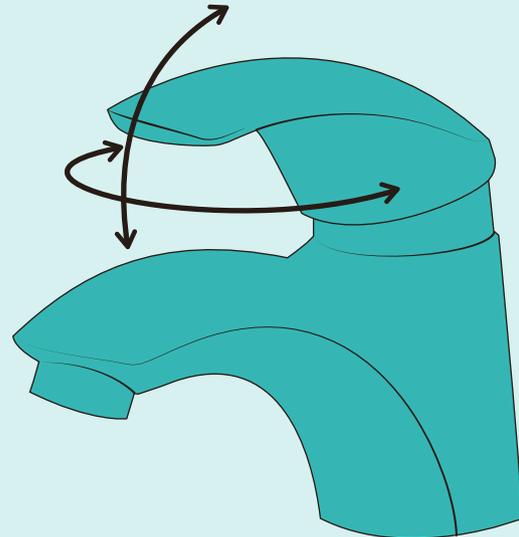
In Suh's Axiomatic Design (1990/2001), there is a mapping between the domains of design, as illustrated below.



EXAMPLE | The bathroom faucet from a users perspective; a non-coupled design

A diagonal A-matrix is sign of a non-coupled design.

$$\begin{Bmatrix} FR_1 \\ FR_2 \end{Bmatrix} = \begin{bmatrix} A_{11} & 0 \\ 0 & A_{22} \end{bmatrix} \begin{Bmatrix} DP_1 \\ DP_2 \end{Bmatrix}$$



METHOD #3

TOLERANCE DESIGN

The use of tolerance analysis ensures the realization of the functionality of the product by taking the impact of variation into account.

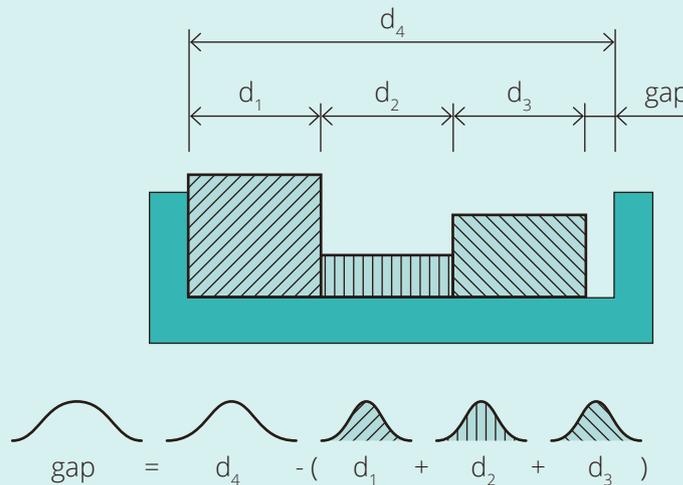
Tolerances should be determined to ensure that the transfer function of the design results in good quality.

Thus, it is possible to assess the impact from various types of variation on the functions of the product.

A chain of dimensions – each with its own tolerances – that has an impact on the function of the product is analysed using a simplified representation of the actual chain.

 Excel – CETOL – VarTran

EXAMPLE | A chain of dimensions



METHOD #4

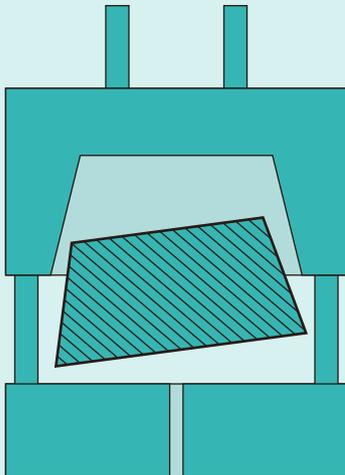
DFM / DFA

The goal of DFM/DFA is to make a product as producible and easy to assemble during production as possible. The checklist includes material and process selection, Poka Yoke, part count, draft analysis, etc.

The capability of the process should be used for tolerance analysis.



EXAMPLE | Part falling out of tool



METHOD #5

FEM / FEA

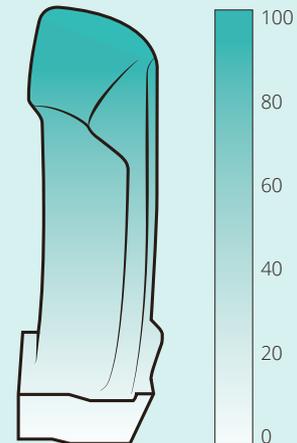
FEM/FEA is a great and efficient tool for strength and stiffness calculations. Different product configurations can quickly be tested and parameters' influences on force balances can be approximated. This results in a preliminary empirical model without the need of physical tests.

Other applications include:

- Heat transfer
- Flow
- Injection molding
- Multiphysics



EXAMPLE | FEM analysis of cantilever snap

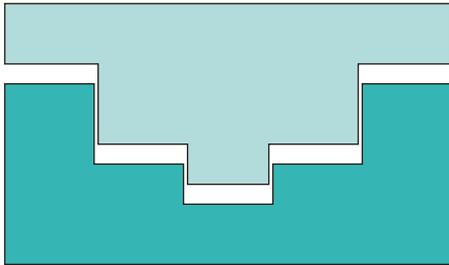


METHOD #6

INTERFACE ANALYSIS

Interface analysis gives an overview of which surfaces of a given part are in contact with surfaces of other parts. This is useful for creating a basis for tolerance analysis and kinematic analysis. The analysis may be performed inside the CAD-system by highlighting each interface in the assembly for improved communication and further analysis.

Question | Which is the functional surface?



METHOD #7

DESIGN OF EXPERIMENTS

Design of Experiments (DoE) is a powerful tool to establish transfer functions. It is founded in statistics and used to find relations between inputs and outputs in complex systems, where an analytical model cannot be established. One of the strengths of DoE is that the number of experiments can be reduced, while maximizing the amount of information gained.

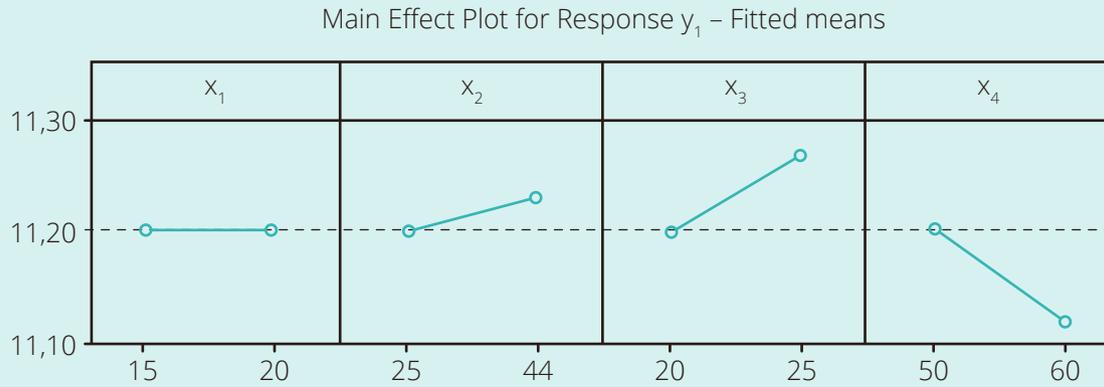
Response surface methodology

The few most significant factors from the screening DoE are further investigated using a Response Surface Methodology (RSM) experiment, which results in an empirical model, used for optimization of robustness.

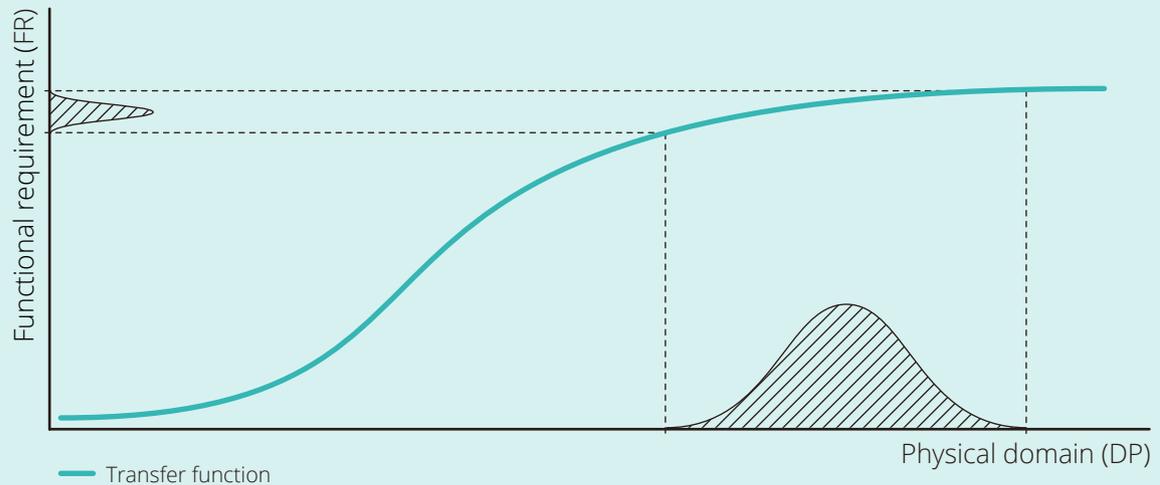
Screening DoE

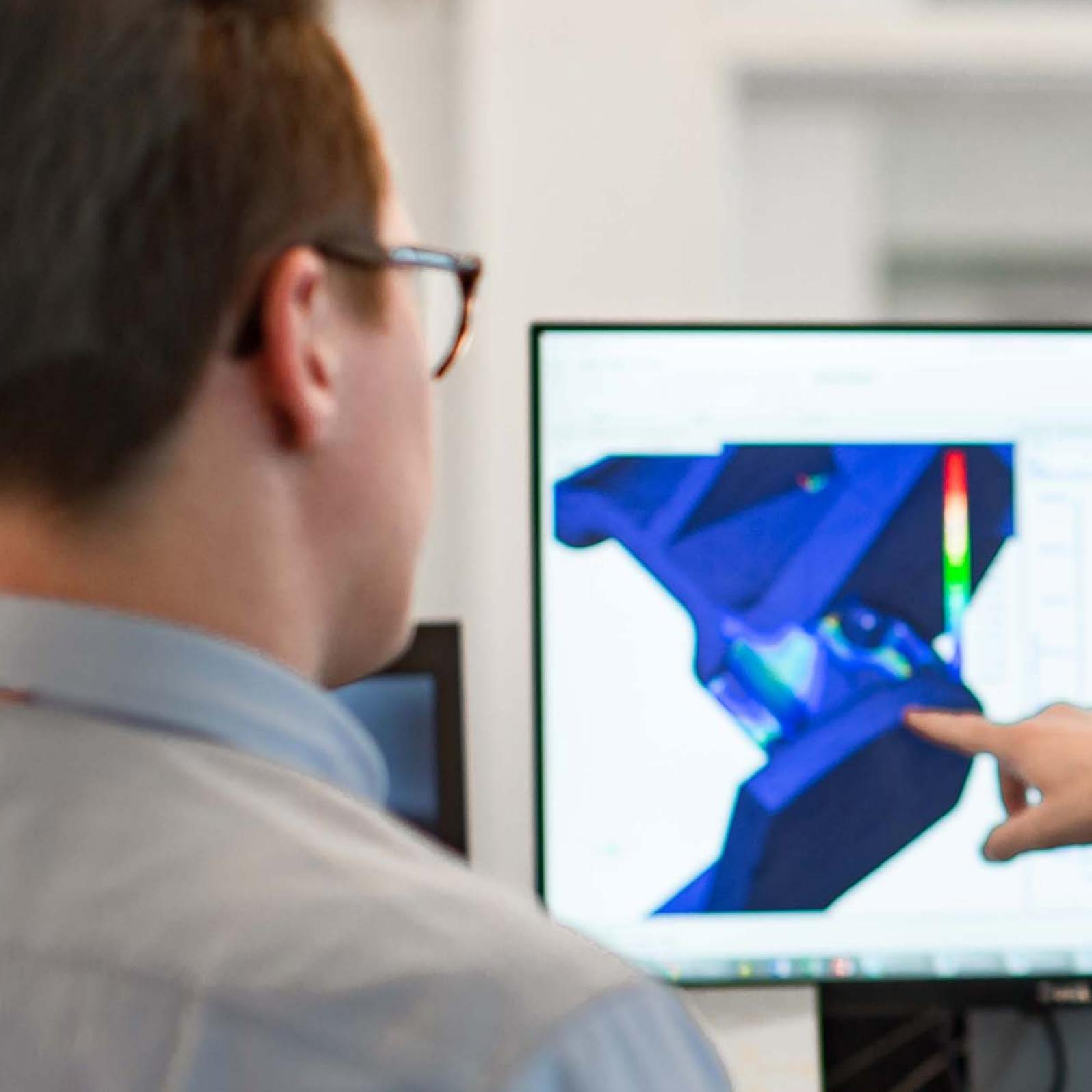
This class of DoE is usually applied to determine the relative importance of each variable, or factor, in the system.

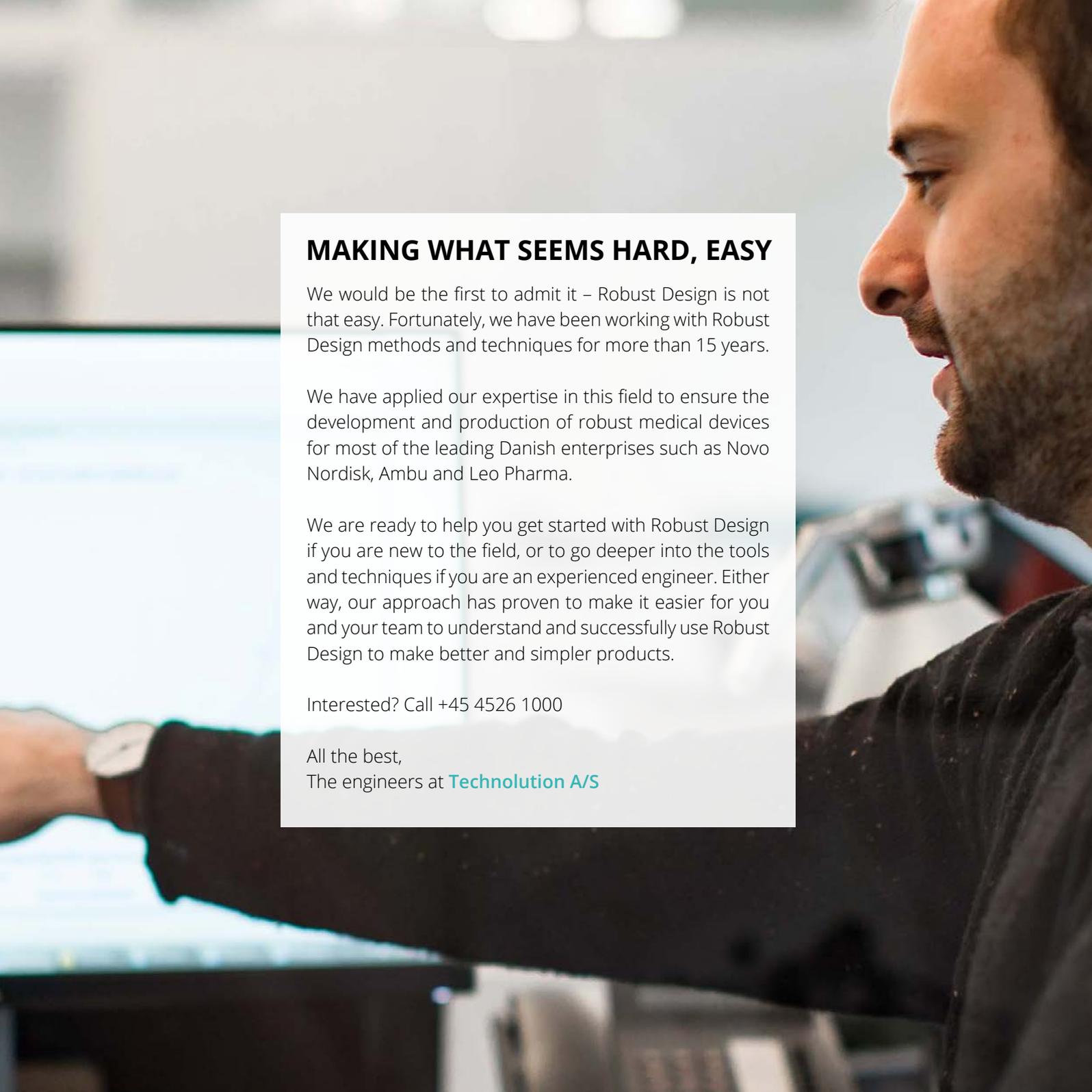
EXAMPLE | Screening of DoE



EXAMPLE | Response surface methodology





A man with a beard, wearing a dark jacket, is shown in profile from the chest up, looking towards the left. He is in a technical or industrial environment, with a computer monitor visible in the background. The background is slightly blurred, showing what appears to be a control panel or machinery.

MAKING WHAT SEEMS HARD, EASY

We would be the first to admit it – Robust Design is not that easy. Fortunately, we have been working with Robust Design methods and techniques for more than 15 years.

We have applied our expertise in this field to ensure the development and production of robust medical devices for most of the leading Danish enterprises such as Novo Nordisk, Ambu and Leo Pharma.

We are ready to help you get started with Robust Design if you are new to the field, or to go deeper into the tools and techniques if you are an experienced engineer. Either way, our approach has proven to make it easier for you and your team to understand and successfully use Robust Design to make better and simpler products.

Interested? Call +45 4526 1000

All the best,
The engineers at [Technolution A/S](#)

The objective of Robust Design is to minimize the sensitivity of a product towards variation factors encountered throughout the life cycle of the product.

If this is news to you, the guide will give you a glance into the world of Robust Design.

If you already know this, the guide is a compilation of the tools and techniques you can use in your daily work as a mechanical engineer.

Either way, we have tried to compile resources that is relevant to YOU. Enjoy.