

Model Based Design Of Medical Devices

A Tata Elxsi Perspective

Tata Elxsi's Solutions - Medical Electronics

Abstract

Modeling and Simulation (M&S) is an important tool that may be employed in the end-to-end development of complex medical devices. Modeling and simulation will reduce time to market and also help in system optimization. This paper provides a brief overview about the role of modeling and simulation in the end-to-end development of medical devices and Tata Elxsi's expertise in this domain.

Introduction

Modeling is the process of representing an object, system or an idea in a form other than that of the entity itself, as a representation of its construction and functioning which may be done partially as an area of interest or in totality.

There are two types of modeling - Physical (Scale models, prototype plants) and Mechanical (Analytic queuing models, linear programs, simulation). Simulation of a system is the operation of a model, which is a representation of that particular system. The purpose of a model is to facilitate the analyst to predict the effect of changes to the system. The model should be a close approximation to the real system and integrate most of its significant features. With respect to the system, it should neither be very complex nor very difficult to understand and perform required experiments on. While the model can be reconfigured and experimented with usually, it is impossible, expensive or even impractical to do so in the system it represents. Though the model helps in studying the model, the properties concerning the behavior of the actual system or its subsystem can be conditional.

Modeling and simulation have been commonly used in various scientific domains, including ecology, social sciences, economics, and engineering. Modeling has been used by healthcare professionals to investigate disease mechanisms and design novel pharmaceutical agents. In sectors such as manufacturing, aviation, and logistics, M&S techniques have led to major improvements in decision-making, efficiency, and quality as a real system is modeled to understand its behavior. The ultimate agenda of M&S is to provide the basis for making technical and programmatic decisions, from the initial feasibility study of the idea to the evaluation of the system to check whether it meets the requirements.

Benefits of modeling and simulation

M&S allows the testing of every aspect of a proposed change or addition to a system without committing resources to their purchase. It also allows speeding up or slowing down the phenomena so that we can investigate them better. Some systems are so complex that it is impossible to consider all the interactions taking place in a given moment. With M&S, we can better understand the interactions among the variables making up the complex system. M&S provides understanding about how the actual system operates, rather than indicating someone's predictions. M&S can be used to determine requirements for a system design by simulating different possible configurations of a system.

Medical device design challenges

The infusion or suction of fluids and gases play an important role in most medical devices, wherever a liquid or gas needs to be measured, monitored or controlled while they are used in any therapy. These are one of the major challenges in the process of medical device design. Fluid handling also plays an important role in applications such as cooling of medical lasers and drug delivery in infusion pumps, as well as for precise delivery of gases in products such as ventilators and in wound management. Among these devices, there is a range of fluid management needs, such as liquid monitoring, mixing and dispensing, wash systems, and waste control; each with its own unique functional properties.

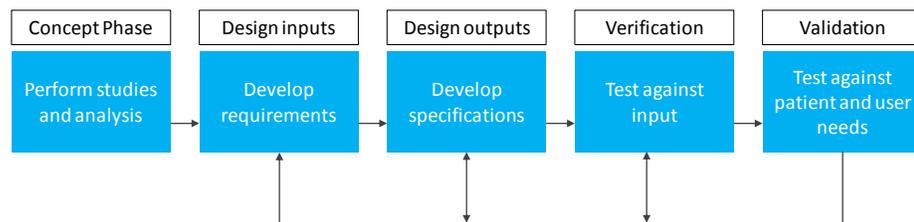


Figure 1. Product development methodology and Tata Elxsi's expertise

The current trend in medical devices and equipment is towards miniaturizing products. In fact, reducing instrument size or complexity can create significant new market opportunities. The challenge for medical device manufacturers is to accelerate time-to-market and stay lean on cost, without compromising quality and regulatory norms. There are several other parameters, the lack of which are challenging the development and market status of the medical device equipments such as:

- Sufficient medical device expertise and suitable skills
- Sufficient targeting of needed medical device innovations
- Sufficient investment (public and private) especially at early stages
- Sufficient incentives to attract and retain industry
- Harmonization (internal and external) with other jurisdictions

Economic impact of medical devices

The medical devices' sector offers significant economic opportunities in terms of sustained market growth, economic diversification, employment expansion, and global export markets. With the proliferation of advanced

medical devices and diagnostic instruments accelerating, laboratories, hospitals, and physicians are demanding a growing array of increasingly complex yet smaller, faster and more reliable systems. At the same time, cost pressures on both Original Equipment Manufacturers (OEMs) and end-users continue to grow. To meet these demands, device manufacturers must increasingly find new ways to innovate design and production while improving efficiency of resource utilization.

Tata Elxsi's Proposed Solution

Case study proposed by Tata Elxsi in Wound Management

Negative Pressure Wound Therapy (NWPT) is a therapeutic technique used for improving wound healing capabilities by means of a suction motor along with tubes to remove wound exudates, causing tissue contraction and improving the formation of epithelial cells or granulation tissue over the wound.

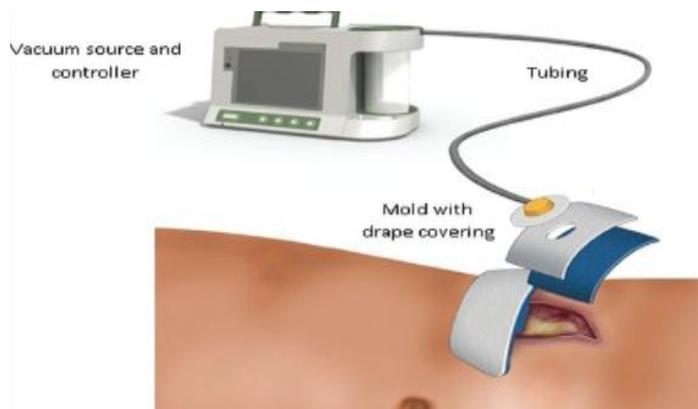


Figure 2. Negative pressure wound therapy setup

Negative Pressure Wound Therapy is a system composing of electronic, firmware and mechanical systems which work interdependently. Such an integration of complex modules often leads to major challenges to a medical device designer.

designer needs to understand the working of the system. This understanding is often complicated by the component-level diagrams that the designers use. By using mathematical models and system models, the designer would get a better understanding.

Challenges faced by NPWT medical device designer

- Difficulty in understanding the Working of NPWT system through component level diagrams
- Design of closed loop system using feedback from pressure sensors
- Testing of NPWT prototype systems in optimum conditions
- Verification of pressure generated by vacuum pump

Before designing the firmware and software for NPWT system, the

The mathematical model of the NPWT system also helps in predicting the optimum pressure generated by the motor in the vacuum pump in ideal conditions. This can help the designer in the formation of a closed loop system. This optimum pressure reading can also be used for verifying the working of vacuum pumping.

Negative Pressure Wound Therapy mathematical MATLAB model

This is a mathematical predictive model intended to understand the working of negative pressure wound therapy by realizing the various physical laws

behind the phenomenon. In this model, we use various physical laws behind vacuum generation and by taking the system and tube geometry into consideration to predict the negative pressure generated at the wound site.

GUI

The GUI contains options like max negative pressure to be generated, wound geometry and set-up time, which can be entered by the users. It also contains canister geometry parameters and tube geometry parameters, which are entered by the user, who can also select the output of the system like air flow at the canister, pressure generated at the canister, as well as the wound.

Tata Elxsi's approach to Model based design of Medical devices and analysis

Tata Elxsi provides a complete custom solution for a variety of medical devices/ instruments under one roof. We provide product design and development support, right from specification definition through hardware/board design, firmware, software, industrial design for packaging, digital signal processing, image processing and control system design. Our quality process corresponds with ISO-13485, 21 CFR Part 820, ISO-14791, US FDA, IEC-60601 series and other equivalent regulations.



Figure 3. NPWT GUI

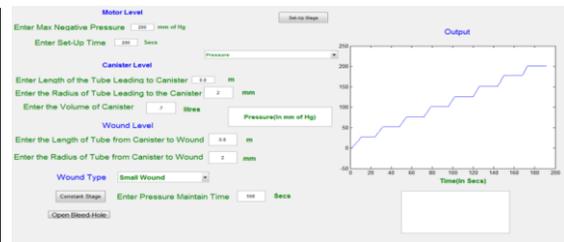


Figure 4. When user enters the significant values

Tata Elxsi's service offerings on model based design of medical devices

The medical device industry is one of the emerging market, leading to the enormous development of patient care and patient monitoring devices. To overcome all these factors, Tata Elxsi provides key trends incorporated with end-to-end product development, cost reduction, miniaturization & portability obsolesces, and remote patient monitoring.

NPWT is the one of the most challenging medical devices, creating several hurdles and changing the market dynamics in wound therapy management. Tata Elxsi's broad vision and unique expertise in product design and engineering services enables it to provide services across the product development lifecycle.

Tata Elxsi provides perfect solutions to the emerging medical markets like diagnostic devices, surgical devices, point of care devices, telemedicine solutions, and medical imaging solutions. It also has functional expertise in the area of product concept analysis, product design requirements, product design specifications, verification, and validation.

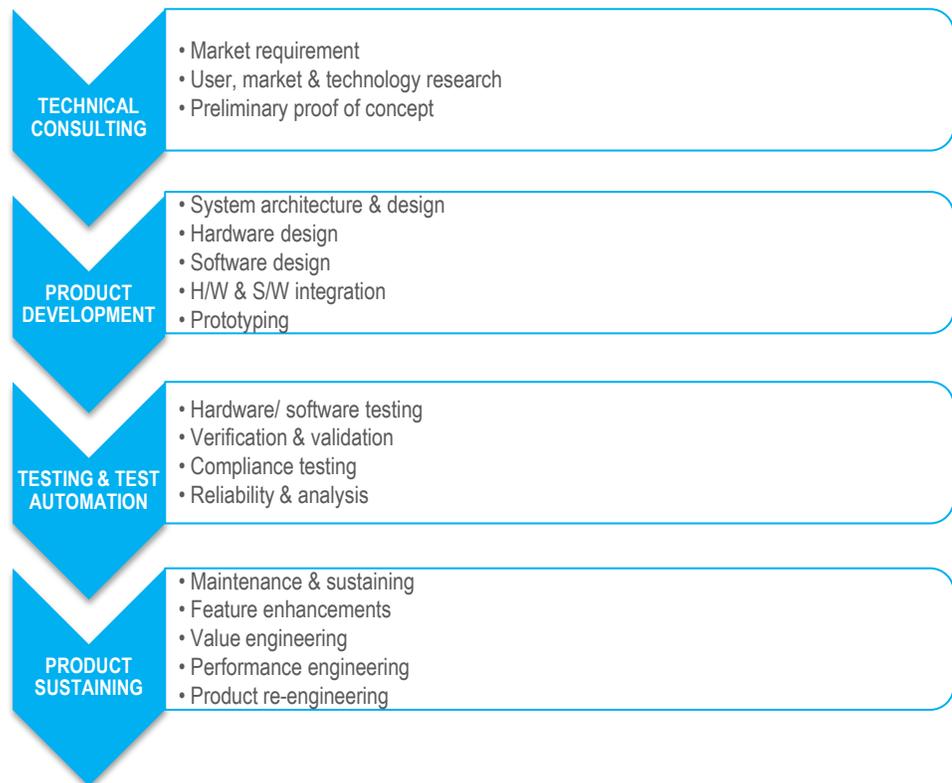


Figure 3. Tata Elxsi product design services & expertise

Case study: Medical device design challenges- Infusion pump

Fluids and gases play an important role in most medical devices. Wherever liquid or gas needs to be measured, monitored or controlled for use in any therapy, it poses as a technical challenge. Fluid handling also plays a vital role in applications such as cooling

of medical lasers and drug delivery in infusion pumps, as well as precise delivery of gases for products such as ventilators. Among these devices, there are various fluid management requirements, such as liquid monitoring, mixing and dispensing, wash systems, and waste control; each with its own unique functional properties.

Tata Elxsi's expertise in modeling and simulation will definitely help manufacturers to formulate design as an executable specification, reducing the time to market while enhancing design flexibility.

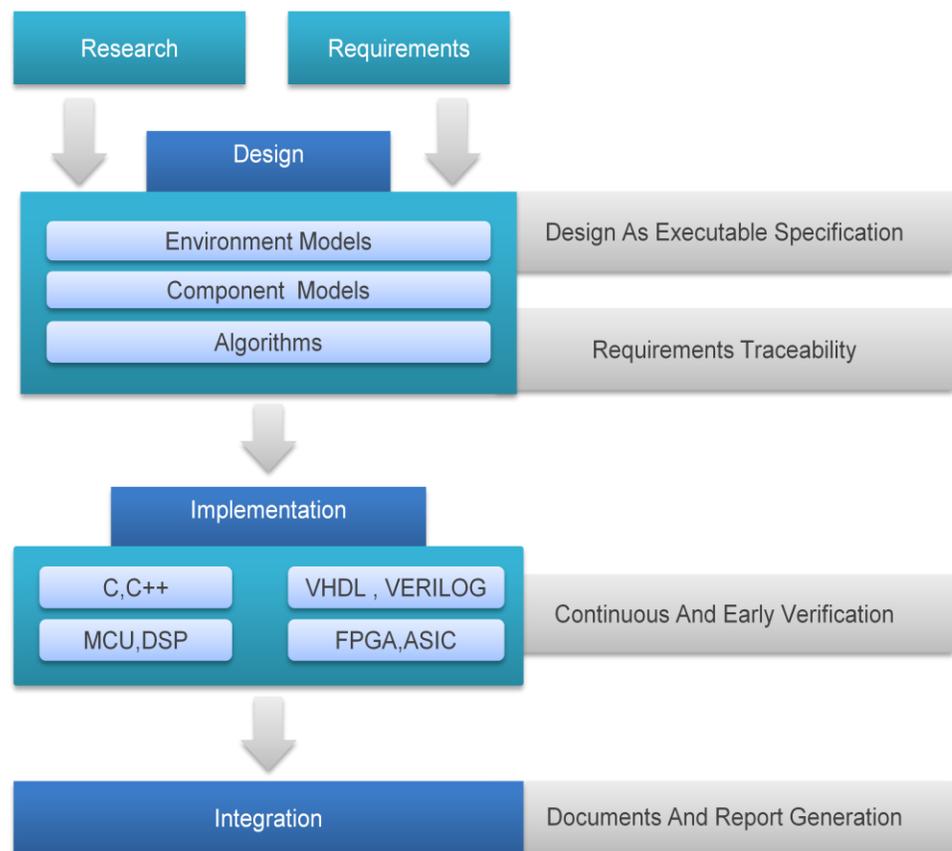


Figure 4. Model based design methodology

Tata Elxsi Medical devices Practice

The medical device industry is one of the most emerging markets in the present comparative world. This leads to the enormous development of patient care and patient monitoring devices.

To overcome all these factors Tata Elxsi provides end-to-end product development, cost reduction, miniaturization & portability obsolesces, and remote patient monitoring. NPWT is the one of the most challenging medical devices which is used in wound management, creating lots of hurdles and changing the market dynamics in wound therapy

management.

Tata Elxsi has expertise in product design and engineering services, and functional domain expertise in product concept analysis, product design requirements, product design specifications, verification and validation. We provide services across the product development lifecycle and perfect solutions emerging market like diagnostic devices, surgical devices, point of care devices, telemedicine solutions, and medical imaging.

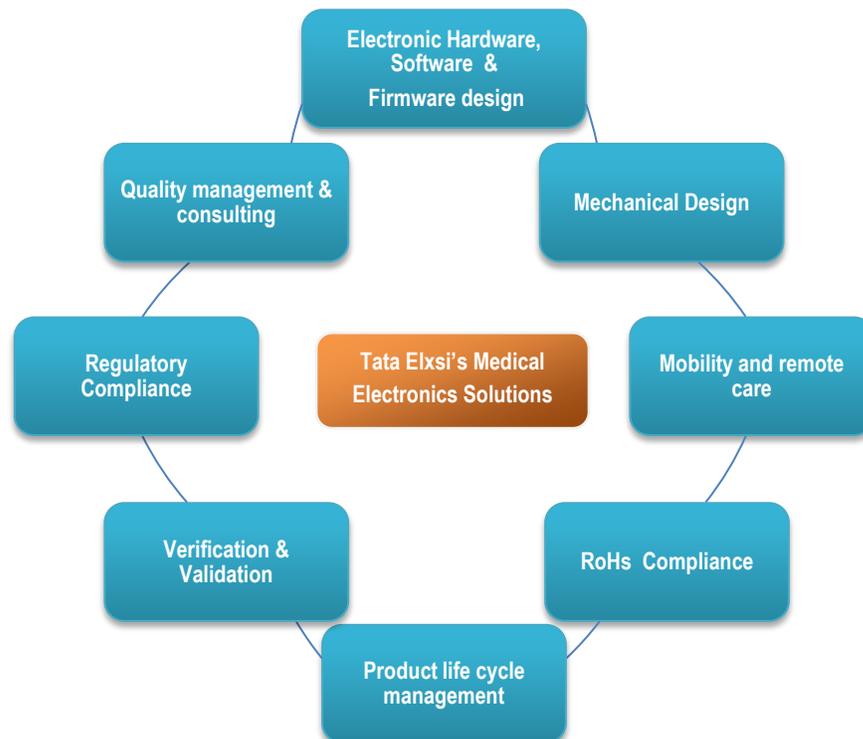


Figure 5: Tata Elxsi Medical Electronics Product design Solutions

Conclusion

Modeling and simulation provide a systematic and integrated platform to accelerate the device development process. The present day healthcare systems and medical device companies are working under financial pressure. Tata Elxsi responds to the healthcare sector by exploring every opportunity to increase efficiency and reduce costs.

The history of medical devices has shown that the winners will be those who can deliver exactly what the customer wants nothing less, nothing more at the best possible price. This new trend is a great challenge in the developed and emerging markets. The success and development in emerging markets require deep understanding of stakeholders' needs. To rise above this problem medical device companies require a new way of thinking about product design. In particular, they need to be able to do two things effectively. First, they must find ways to understand exactly which product features their customers need and the second how much they are willing to pay for that particular product or device.

References

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About the Author

Tata Elxsi's Medical Devices Practice has a multi-functional leadership team with a combined domain experience of more than 200 person years. Tata Elxsi's solution team works with medical devices OEMs to solve the challenges and pain points in the dynamic medical device domain.

With proven expertise in monitoring, therapeutic and diagnostic medical devices backed up with a thorough understanding of the geography/country specific regulatory requirements, the solutions team encompasses interdisciplinary skills which play a pivotal role in conceptualizing and developing service offerings for the medical device domain.

Contact us

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About Tata Elxsi's medical devices engineering services offerings

Tata Elxsi provides design and engineering services to the medical device industry. We understand the changing trends in this industry and offer services such as concept generation & validation, product development, verification & validation, and sustenance engineering.

With a unique focus on product design and engineering services, we provide services across the product development lifecycle. We have leveraged our cross-functional domain expertise in the areas of connectivity technologies (Bluetooth, Wi-Fi, wireless), mobility solutions, and industrial design to provide cutting edge solutions to our clients spanning Diagnostic & imaging, ventilator, infusion pump, therapeutic, surgical equipments, point of care, endoscopy, diabetes devices and tele-health solutions.

About Tata Elxsi

Tata Elxsi is a design company that blends technology, creativity and engineering to help customers transform ideas into world-class products and solutions.

A part of the \$100 billion Tata group, Tata Elxsi addresses the communications, consumer products, defence, healthcare, media & entertainment, semiconductor and transportation sectors. This is supported by a network of design studios, development centers and offices worldwide. Key services include embedded product design, industrial design, animation & visual effects and systems integration. Tata Elxsi is a listed company and headquartered in Bangalore, India.

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