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Investigations of Base Simulation CAD Packages for Initial Regulatory Feasibility Testing in Medical SMEs.

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Abstract: The development of medical devices is a complex and highly regulated process, often requiring skilled engineers to conduct advanced analyses for mechanical safety and efficacy. However, med-tech SMEs with limited resources face challenges in navigating these requirements. Industrial designers play a crucial role in making devices both functional and competitive by incorporating ergonomics, aesthetics, and user comfort, and recently basic FEA analysis. To support this, we propose a framework showing how Industrial Designers can utilize basic linear and static simulation tools, allowing for iterative design refinements that align with regulatory standards before significant investment.

Keywords: CAD Simulations, Simulated Regulatory testing, Medical Device engineering, Mechanical engineering.
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1 INTRODUCTION

Industrial designers play an important role in developing medical devices, not only for function but also in ensuring the product is competitive. We propose integrating basic simulations into the *Ideation* or *Development* phase, enabling designers to conduct broader early-stage evaluations to iteratively refine outputs prior to the final testing phases, where more complex simulations can be performed in collaboration with expert analysts.

The use of SimulationXpress for medical device regulatory testing isn't explored; however, the use of CAD simulation methodologies in medical device development and regulatory evaluation is explored, often focusing on FEA, CFD, and MBS, which are conceptually like SimulationXpress. As a comparative assessment, these examples present a new way to utilise add-ons from SolidWorks,

widely used CAD package in industry and in smaller to medium enterprises (SMEs) and data exchange is crucial between suppliers and manufacturers [5]. Though SolidWorks is not a top-tier solution, and other far more advanced CAD packages exist, SolidWorks is heavily utilized in SMEs and is one of the most widely used and respected CAD tools globally. Research has shown that Solidworks has a broader range of modelling and assembly features, though the free-simulation versions still have limited mesh handling which can restrict the analysis capabilities [7] when compared to other more advance packages such as Ansys. Solidworks can also handle complex assemblies without overloading the CPU, noted for its direct-edit and free-form approach, enabling less constrained, but also less accurate outputs [8].

While CAD simulation software offers significant benefits, such as improving product design, reducing prototyping costs, and speeding up development, SMEs (Small to Medium enterprises) face several barriers to adopting these tools. CAD simulation packages often require highly skilled engineers with years of experience to operate the boundaries for testing appropriately and to interpret the results for correct implementation. Previous research suggested approaches to overcoming the challenges of integrating CAD packages for product development [6]. High upfront and ongoing costs, steep learning curves, limited technical resources, and the complexity of integration and support can make it challenging for small businesses to fully embrace CAD simulation [6]. To overcome these hurdles, SMEs may consider starting with low-cost or less advanced simulation software that can be operated by industrial design teams seeking training, or leverage cloud-based solutions that reduce the need for heavy initial investment in hardware.

When investing in regulatory testing, high costs, resource limitations, complexity, and uncertainty in evolving standards can be challenging to address. SMEs need to work with independent test labs and skilled engineers to efficiently manage expensive regulatory testing with no guaranteed success. Industrial designers can potentially exploit several CAD packages that can iteratively develop outputs and quantify assurance in design aspects prior to progressing a device to the regulatory pathway, which is an inevitable and necessary expenditure for the commercial sale of medical devices. Generation of various geometries and topologies can enable several analyses on different aspects of design outputs alongside a list of applicable regulatory standards, thus enabling a simplified approach to navigating regulatory standards and de-risking resource allocation for SMEs.

1.1 Problem Definition

Research has evidenced the benefits and versatility of skillsets that industrial designers can bring to SMEs [16]. Medical design demands a highly skilled design engineering team to ensure device safety and efficacy, often requiring high costs and resources. The objective of this study is to investigate ways to test and validate crucial applicable regulatory standards through design aspects within base simulation packages. Regulatory testing is subsequently conducted in approved test laboratories governed by notified bodies. When devices have reached a design freeze, designers provide specifications and Beta prototypes for various regulatory tests. When the resulting parts fail to pass a test, often as a direct result of suboptimal design, then the SME will need to rework and provide subsequent batches of improved products, evidencing sufficient mitigation of failures. This may require further tool changes, manufacturing costs, sample production runs, engineering resources to provide design changes and evidence, and repayment of the external test labs to reconduct the regulatory tests.

SMEs often struggle to justify investment into advanced CAD packages, particularly advanced simulation tools such as CFD, limited by constraints in time, financial resources, and technical expertise. These upfront license costs, ongoing maintenance fees, and potential hardware upgrades can be prohibitive. However, CAD providers are moving towards pay-per-use models such as simulation credits or term licenses, which will help SME adoption. Teams in SMEs often operate with lean employees who wear multiple hats, making it difficult to allocate time for training on complex design software packages. Often, the ultimate decision is that even if the tools could improve productivity or product quality, the immediate resource burden can deter adoption.

An SME R&D team may include <5 staff, whereas a large to medium enterprise may consist of >30 R&D staff. Subsequently, SMEs rarely employ FEA or CFD trained persons in their design process, but when it is needed, an educational partner or consultants may be employed as external expertise. Without dedicated design personnel, the learning curve associated with powerful CAD systems like SolidWorks, Siemens NX or similar can seem daunting. This can cause hesitation or additional risk for underutilization of these tools, which may be only partially used, which doesn't yield a clear return on investment. This knowledge gap often leads SMEs to rely on simpler tools, outsource design work, or delay adopting robust CAD solutions.

The team developed a framework to help Industrial Designers incorporate CAD simulations into various aspects of regulatory testing within a virtual environment to ensure robustness through developed safety and efficacy. By simulating specific regulatory tests, this approach enhances confidence in design outcomes before committing to costly external testing. Basic entry-level simulation tools are evaluated to reduce steep learning curves associated with conventional CAD packages, lower early investment, and streamline the development process. Thus, providing more resources to allocate to the inevitable high investments in regulatory testing. Design output confidence is assured through quantitative metrics provided by simulation packages, where factor-of-safety (FOS) can be provided against stipulated test parameters in medical regulations. The aim of this paper is not to evaluate the CAD packages, but rather to provide a map for how to evaluate the regulatory needs and technical testing elements required in the early design phase for medical devices and how to navigate these within a 3D virtual environment to streamline the rigor of testing and reduce the required resources.

2 DESIGN CONSIDERATIONS

2.1 Regulatory Considerations

As medical devices predominantly fail regulatory testing from design-related faults, Mechanical Engineers and Industrial Designers play a crucial role in developing devices that are safe, functional, reliable, and efficient. CAD simulation packages are essential tools in the development of medical devices, offering benefits across the entire product lifecycle, from design and prototyping to testing, manufacturing, and regulatory compliance.

The medical design process is long, stringent, and expensive, with designers having to overcome a list of hurdles prior to sale on the market. Studies show that it takes 3-7 years to bring a device from concept to approval [9]. The average cost of bringing a class II device to market from concept to market is between $2-5 million [4]. Medical devices are governed by a plethora of regulations, where design and development can be a slow process to ensure compliance. The approach presented in this work can assist in navigating most applicable standards; some of the following examples are considered key medical device regulatory standards: BS-EN:60601-1, ISO:13485, IEC:14971, and IEC:62366 [12]. BS-EN:60601-1 (safety and essential performance requirements for medical electrical equipment) is a critical step in the development of medical devices, ensuring that these devices meet essential safety and performance criteria such as mitigation of potential electrocution, crushing, structural integrity, improper use, and more. Passing these tests is necessary for regulatory approval and market acceptance, and safeguards both patients and healthcare providers [14].

SimulationXpress is a basic simulation tool designed primarily for entry-level analysis. One of its major limitations is that it only supports static stress analysis for single-body parts, restricting its usefulness for evaluating real-world mechanical systems such as nonlinear simulations. Additionally, it supports only linear materials and assumes small displacements, making it unsuitable for analysing plastic deformation, large deflections, or non-linear material behaviour.

2.2 CAD Simulation Packages

CAD plays an important role in the Industrial Design Process and aims to deliver innovative, user-centred products that are practical to produce. It is a useful tool to complement the research into new product development. The application of CAD has been studied previously by many researchers, including CAD, but not how Industrial Designers could utilise the technology for simulating regulatory testing using linear, static, base-level simulation packages.

Entry-level simulation tools like SimulationXpress can offer valuable support to SMEs developing medical devices, particularly during the early stages of product design. Enabling basic static stress analysis on individual parts allows designers to quickly evaluate whether a component can withstand expected loads without failure. This can help identify weak points in a design before physical prototyping, saving both time and material costs. For SMEs with limited budgets and resources, this initial level of virtual testing can be a cost-effective way to iterate and improve designs, especially for non-critical components that don't require rigorous validation.

Additionally, SimulationXpress can help SMEs build confidence in digital design processes and lay the foundation for more advanced simulation practices in the future. Even though the tool cannot handle complex assemblies or perform comprehensive regulatory-level analyses, it introduces teams to the principles of finite element analysis (FEA) and promotes a design-for-performance mindset. For medical device startups or smaller manufacturers, this can be particularly useful for rapid prototyping and feasibility studies, where quick insights into structural integrity are sufficient to move forward. While it cannot replace full regulatory testing, it helps SMEs make more informed design decisions early in the development lifecycle, potentially reducing the number of costly design iterations later.

CAD simulation testing offers several key advantages over physical testing, particularly in terms of speed, cost, and flexibility. One of the most significant benefits is the ability to evaluate design performance virtually before any physical prototypes are manufactured. This allows engineers to identify and correct design flaws early in the development process, significantly reducing the number of costly prototype iterations. Simulation also enables rapid testing of multiple design variations under different load conditions, which would be time-consuming and expensive to replicate physically. For SMEs and startups, this virtual approach can be especially valuable, helping them optimize designs within limited budgets and timelines. Another major advantage of simulation over physical destruction testing is the ability to visualize and understand internal behaviours that are difficult or impossible to observe in real-world testing. Stress concentrations, deformation patterns, and thermal gradients can all be examined in detail, offering deeper insights into why a part might fail. Additionally, simulation supports a broader range of scenarios—including extreme conditions or long-term fatigue—that may be unsafe, impractical, or too expensive to test physically. While physical testing is still essential for final validation and regulatory compliance, CAD simulation provides a powerful tool for front-loading the design process with more informed decisions and greater innovation potential. CAD and simulation tools are transformative for SMEs in the medical device sector, accelerating design, meeting regulatory requirements, enhancing collaboration, and driving innovation. 3D simulation enables virtual testing and optimization across various engineering challenges, with specialized CAD and simulation software tailored to meet the specific needs of different industries. These tools ensure high performance, accuracy, and efficiency for unique applications, with software selection based on factors such as design complexity, simulation types, materials, and manufacturing processes. This research focuses on stress analysis, including linear and nonlinear simulations to assess mechanical integrity, airflow simulations for heat dissipation and noise reduction in medical device design. By concentrating on these areas, the study provides insights to improve performance and reliability in early-stage development.

Simulations play a crucial role in the design and development of wearable medical devices throughout their total product life cycle aiding in device development, design optimization, and regulatory decision-making for peripheral devices [10]. Significant advancements in simulation, and computational modelling can provide a powerful tool to efficiently explore designs, predict

performance, supplement physical testing, support regulatory decisions, and evaluate post-market changes in medical devices. CAD simulation packages are heavily utilized for design validation, and for advancing regulatory science for medical devices in FDA laboratories [15]. Design for regulatory compliance is a rare skill set required for SMEs to navigate regulatory requirements in the design of devices. Finite Element Analysis (FEA) simulations can help predict device behaviour and validate designs without physical prototypes [3] FEA is also employed to assess structural integrity and improve designs [2]. Additionally, automated web-based simulation tools following regulatory standards can streamline the process, requiring minimal modelling expertise [1].

Several levels of simulation tools are available, ranging from premium packages like Siemens NX, Creo, and CATIA, to mid-level software such as SolidWorks and Autodesk. There are also other standalone tools (e.g., Simul8), although these are not included in this work. This study focuses solely on assessing a basic package. When comparing SimulationXpress with the full SolidWorks simulation suite and other advanced 3D simulation tools, SMEs must carefully consider their specific needs, budget, and industry requirements. SimulationXpress offers an entry-level solution for basic linear static stress analysis, making it ideal for industries where simple structural validation could be enough for consumer product design, basic mechanical components, or general manufacturing. In contrast, full SolidWorks simulation and more advanced FEA/CFD (Computational Fluid Dynamics) packages provide greater capabilities, including nonlinear analysis, thermal simulations, and dynamic studies, which are essential for industries like aerospace, automotive, or heavy engineering.

Industrial designers can leverage these basic simulation tools to assess product feasibility without the need to employ highly qualified engineers with specialized simulation experience [13]. User-friendly interfaces and automated setup processes allow designers to perform preliminary stress, flow, or thermal analyses, enabling faster iteration in the design phase. However, depending on device classifications, highly regulated Class III medical devices may require more advanced simulation tools where external collaboration may be needed. Some industries may never need advanced simulations if their products only require basic stress, flow, or thermal analysis, making lightweight tools a practical and economic choice.

3 METHODOLOGY

Design Thinking, Double Diamond, and Waterfall methods are commonly used in the design process, where testing typically occurs in the final phase. These processes guide teams through ideation, researching user needs and market trends, generating and refining product concepts, and developing designs that balance aesthetics, functionality, and manufacturability, prototyping, and testing, with testing typically occurring in the final phase. However, testing at later stages can delay the identification of issues. Integrating simulations and basic testing in earlier phases can provide valuable insights, reducing costly revisions later. This shift toward earlier testing helps mitigate risks and ensures a more reliable design before significant investment. Additionally, companies may use established methodologies like Design Science, which, alongside frameworks such as the one proposed (Figure 1), helps designers navigate regulatory standards like BS-EN:60601-1 for safety and essential performance. The following framework (Figure 1) has been developed to assist in navigating regulatory testing through CAD for the medical design process, which was identified as a requirement in literature [11]. Comprised of 5 main steps, each core section has separate sub-steps that progress through scoping, defining tests, integration into CAD, evaluation and transfer.

As knowledge exchange, this could offer other researchers and SMEs the insight to ‘should I use simulation’. As CAD is an industrial tool first and foremost, these tools can provide investment assessment and ROI profiles necessary for multiple teams including regulatory teams, production staff, engineers and designers. These early-stage validation activities can provide suitable rationale for investment and adoption. Novelty is in terms of context and explores on how SMEs with a lower maturity level of CAD/CAE implementation experience such transformation.

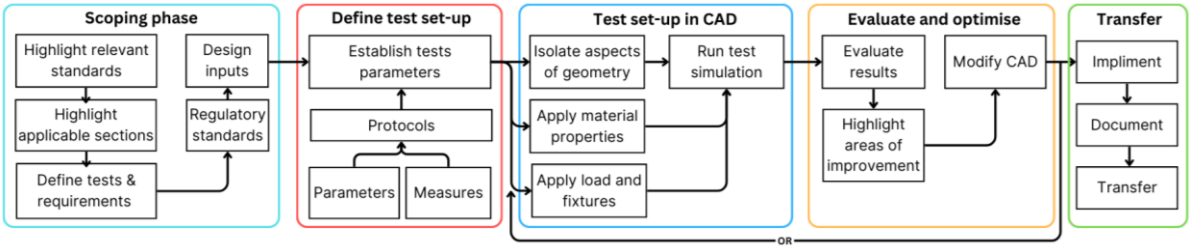

Figure 1: Framework for navigating regulatory testing through CAD.

Regulatory testing ensures the safety of the devices being developed through risk assessment. When evaluating the design, interpretation, and anticipation of potential weaknesses in the design should help navigate the appropriate applications of the test parameters. When a device is sent off for regulatory testing, a laboratory will use certified equipment designed to test against the specific data required in the standard. They can conduct numerous repeat tests at any point on the enclosure, defining how much force, surface area, and duration of exposure of the force upon the enclosure. This specific framework application will focus on IEC:60601-1 mechanical strength, impact, push, and drop, where the standards define boundaries and parametrization for the virtual protocol.

For this study, SolidWorks modelling and SimulationXpress are carried out, but the successful use of the entry-level tools is expected to demonstrate the transferability of skills to other software packages. A vent grill design was iterated and tested in SolidWorks to assess the optimal balance between airflow and strength, ensuring maximum surface area for airflow without compromising the Factor of Safety (FOS) in FEA testing. The designs were further evaluated by measuring the cooling capacity of the condenser for which the vents were designed.

SMEs in the medical device sector frequently collaborate with academia and consultancies for a variety of reasons. These partnerships help address resource limitations by providing access to specialized expertise, knowledge, and advanced software tools that might not be readily available in-house. In an industry that is both highly competitive and fast-paced, such collaborations are essential for staying ahead of technological advancements and evolving market demands. Additionally, these partnerships play a crucial role in enhancing innovation and improving efficiency, enabling SMEs to tackle challenges more effectively. By leveraging external expertise, SMEs can navigate complex regulatory landscapes, ensure compliance with safety and performance standards, and mitigate potential risks. Ultimately, these collaborations help SMEs accelerate product development, reduce costs, and achieve faster time-to-market, improving their ability to compete in the global medical device market.

4 DESIGN & DEVELOPMENT STUDIES

The simulation outlined below is a key component of a cooling device designed to support the treatment of Chemotherapy-Induced Peripheral Neuropathy (CIPN) and Chemotherapy-Induced Alopecia (CIA), where cooling is delivered using wearable devices. These wearable devices have been specifically designed to reduce the temperature of the scalp and extremities during chemotherapy treatment. By cooling these areas, the device aims to prevent or alleviate the side effects of chemotherapy, such as hair loss (CIA) and nerve damage (CIPN), both of which are significant concerns for patients undergoing cancer treatment. Figure 2 below shows the Paxman Limb Cryo-compression System (PLCS) used in this design study, where several simulations are conducted. The enclosure of the device requires a ventilation design. Though 10 vent iterations were evaluated in the larger study, 3 versions are evidenced in this work. Prior to designing,

airflow against a vapour compression system condenser was calculated using the CFU equation for HVAC systems. This provided boundary conditions for minimum airflow surface area against a given condenser surface area to accommodate heat removal from a HVAC system. From these conditions, various vent grill options were designed in SolidWorks and simulated for stress testing conditions.

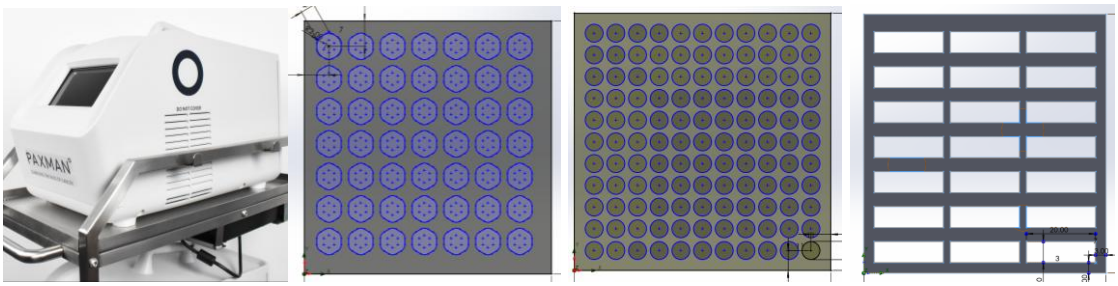

Figure 2: Vent grill options explored (A,B,C).

Figure 2 illustrates the 3 most suitable iterations selected for testing. Ventilation grills can typically introduce more risk through weakness in mechanical strength. Ventilation design has its own section in BS-EN:60601-1 for this reason. Failure under stress could cause exposure of electrical components or moving parts. The design conditions for these vents were to achieve airflow of 8-13 CFM, with a FOS of ≥ 2∼3 against the regulatory standard IEC:60601-1. 3 design options were explored (Honeycomb A, circular B, rectangular C), shown in Figure 2, where all thicknesses are 3mm.

4.1 General: Structural Verification

Using basic FEA validation in SolidWorks, all three vent options were evaluated against the specified design requirements, ensuring a Factor of Safety (FOS) of ≥ 2∼3. Figure 3 below shows the base simulation tools employed to meet the general mechanical strength requirements for ME equipment, where it is stated that parts shall have adequate mechanical strength.

Test boundaries for external parts of the enclosure were subjected to a steady force of 250 N applied via a suitable test tool that provides contact over a 30 mm diameter circular plane surface. However, this test is not applicable to the bottom of an enclosure for ME equipment with a mass greater than 18 kg. The test conditions were defined based on pre-determined moulding material, the applied force, and force calculation using Poisson's Ratio (0.39), alongside the specification of fixings. Following this, a deformation scale and Factor of Safety were determined, with an ideal output of FOS > 3. This would provide sufficient confidence levels against the risk assessment in accordance with ISO 14971 for further progression.

Specific extracts from the standards were utilized during the scoping phase, helping to define test protocols such as material, loads, and test conditions for the virtual testing environment. Figure 3 below illustrates the test parameters, where a 30N load was applied to different locations on the vent grill. These locations were selected based on perceived weak points, which were areas with minimal potential surface contact with the test equipment, resulting in maximum force distribution to minimal surface areas.

The testing enabled the team to optimize key factors, such as wall thickness, device case material selection, and support structures. Figure 3 shows the simulations conducted on the vents for repeat testing. Within the framework for the quality management system ISO:13485, the processes for design and development will inform a medical R&D team on their standard operating procedures. Within this, design inputs are crucial measures used to inform the design outputs and, in turn, the validation and verification parameters.

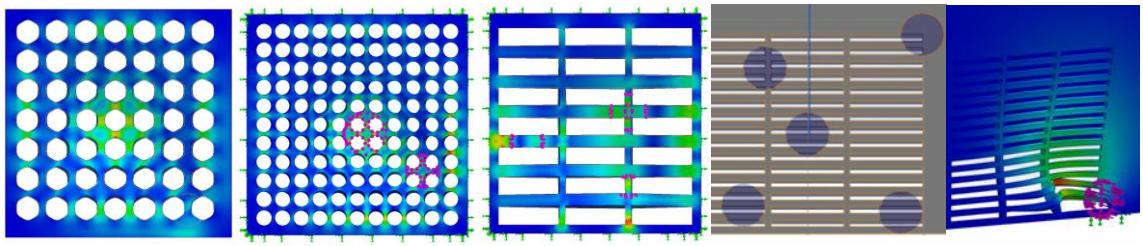

Figure 3: Structural verification using basic static simulation.

4.2 Advanced Simulation Testing

In collaboration with the University's R&D experts, flow simulations were conducted on the channels to assess maximum flow and minimal noise. The relevant fan speed, volume, and pressure parameters, identified by the partner institution, were utilized in the simulation. The results indicate significant vortex formation in Models B and C, while Model A, with its circular design, exhibited no vortexing. The initial analysis suggests that vortices in Models B and C form due to the opening structure. The circular opening in Model A facilitates smoother airflow, with minimal separation, resulting in a smaller vortex zone and more consistent flow. In contrast, the prongs and corners in Models B and C cause local flow separation, leading to interference as the flows converge, thereby generating small-scale vortices or reflux zones.

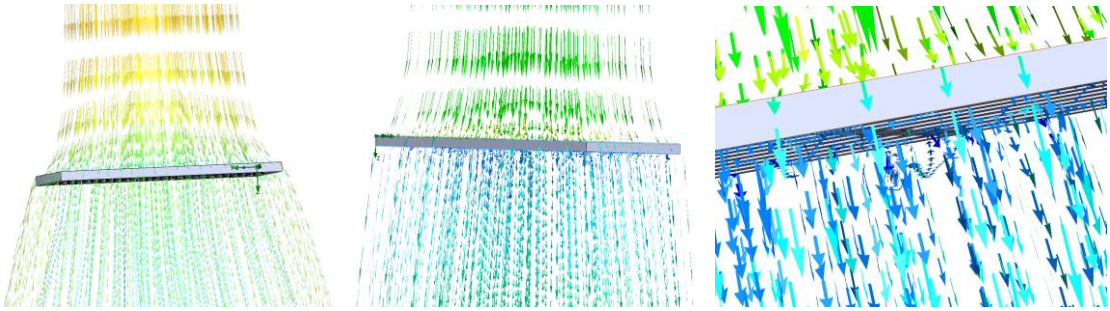

Figure 4: Advanced test comparison – Flow analysis.

This analysis required advanced engineering expertise to define not only the operational parameters but also the boundary conditions, making it outside the scope of an SME's Industrial Design team to implement. However, the simulation provided valuable insights into whether the selected design would meet both performance testing and user requirements, particularly regarding noise reduction. Use of these premium simulation packages has been applied to demonstrate the benefits compared to the basic packages. Premium packages offer specific and highly valuable inputs to the design process that simpler packages and even practical approaches cannot provide (e.g., airflow issues).

4.3 Physical Testing

After completing the virtual testing phase, a physical prototype is developed using 3D printing with materials that closely resemble the final product to ensure accurate mechanical performance during testing. This prototype undergoes a series of physical validation tests, including impact testing and drop testing, conducted in-house to evaluate its durability and structural integrity under real-world conditions.

The drop test evaluates the prototype's structural integrity when subjected to accidental falls from a predetermined height. The test sample, safe working load, is subjected to a free-fall drop from three different orientations that reflect normal use conditions. The drop height is determined by either the operational height specified in the accompanying documents or 1 meter, whichever is greater. The sample is dropped onto a 50 mm ± 5 mm thick hardwood board with a density greater than 600 kg/m³, positioned on a concrete or similarly rigid base. This test evaluates the mechanical robustness, impact resistance, and structural integrity of the equipment under real-world usage conditions.

Physical tests (Figure 5) provided crucial feedback for iterative design improvements, ensuring the final product meets safety, reliability, and regulatory compliance standards before mass production. SolidWorks Simulation, discussed previously, helped rapid evaluation of product behaviour under impact and drop conditions, reducing the need for extensive physical testing. It is particularly beneficial for SMEs, offering quick iterations and seamless CAD integration to enhance product durability before costly prototyping. While it primarily handles elastic deformations and requires accurate material data, it provides an accessible solution for early-stage design validation, with advanced FEA tools needed for highly nonlinear materials.

Figure 5: Push, Finger, and Drop test (Physical testing examples).

5 DISCUSSION

Industrial designers and engineers play complementary roles in the medical device development process, particularly in SMEs where resources and expertise may be limited. Industrial designers focus on user-centred design, ergonomics, and aesthetics, while engineers ensure structural integrity, functionality, and regulatory compliance. By working together, they can leverage accessible 3D simulation tools early in the design process to identify potential design flaws before costly prototyping; however, particularly smaller SMEs may only have a smaller team without an Engineering background.

Advancements in user-friendly simulation software enable non-experts to conduct basic FEA and CFD within CAD environments like SolidWorks Simulation, reducing reliance on specialised engineers for early-stage testing. Engineers, from industry or academia, can support SMEs by providing consulting services, training, and validation to ensure accurate simulation results. Collaborative research projects, government-funded initiatives, and incubator programs further help SMEs access advanced simulation tools without high upfront costs. The integration of designers with accessible simulation technology allows for faster iterations, improved product reliability, and more efficient regulatory navigation, ultimately accelerating time-to-market.

CAD packages are first and foremost a tool for industry, and they need to be accessible. Simulation tools are often denied by smaller companies as they are too expensive and a risk-averse investment for smaller companies. As regulatory testing is a necessary procedure, expensive, and time-consuming, we propose that SMEs can get access to these simpler tools with CAD packages they will already use, without the need for a large upfront investment. SolidWorks

was evaluated, where CAD is often a necessary investment for SMEs looking to embed R&D internally rather than externally, conventionally. SimulationXpress was explored as it comes as standard, without unnecessary investment, giving MedTech organisations a chance to answer the question "do I need simulation tools?". They can use these tools to evaluate before and provide certainty or confidence in their device passing.

The use of FEA is studied by many researchers. This research shows challenges and opportunities for employing Simulation packages in an SME commercial setting, and how an SME in the medical industry can benefit from the research shown here. The use of SimulationXpress for regulatory testing in medical devices is unexplored, providing a novel approach to how Industrial Designers can utilise basic simulation tools in industry.

Some industries only require basic validation, making complex simulation software an unnecessary expense. Industries like medical and aerospace require certified testing beyond what SMEs' in-house simulation capabilities can provide, often requiring external partners or collaborations to conduct these more advanced simulations. For SMEs, using 3D simulations can be a game-changer, but it is crucial to balance cost, expertise, and industry needs before fully committing.

This research focus is not on the evaluation of various CAD and FEA packages for SMEs, but rather on how Industrial Designers can implement basic Simulation packages early in the design process. After evaluating SimulationXpress for the development of a medical wearable enclosure, utilising parameters from pre-defined protocols for medical device regulatory standards, the team highlighted several pros and cons for SMEs to be able to utilise the offerings of free, basic packages, and when to invest in standard or premium simulation options. A preliminary evaluation has been conducted on these packages, only to indicate feasibility assessment within specific extracts of medical device standards. To provide a more definitive and comprehensive finding on the benefits of all aspects would require a much broader multi-disciplinary output, which was out of scope for this project. This evaluation can support other SMEs on how to navigate similar standards and how to apply basic linear simulations for their projects prior to further investment or selection of suitable packages for their applications. Table 1 below compares the differences between SimulationXpress, SolidWorks standard Simulation, and Premium Simulation Packages based on key metrics such as accuracy, ease of use, and time to complete simulations.

Feature metric	*SimulationXpress (Basic)*	*SolidWorks Simulation (Standard)*	*Premium packages (E.g. ANSYS)*
Accuracy	Low: Limited to linear static analysis	Moderate: handles non-linear materials and more advanced constraints	High: supports complex, real-world physics and multi-physics simulations
Ease of Use	Very easy: Guided setup for beginners	Moderate: requires some engineering knowledge	Complex: requires expertise and training
Time to complete	Fast: Simplified analysis with automatic settings	Medium: more setup required but still user-friendly	Long: computationally intensive, requires powerful hardware
Types of Analysis	Basic stress analysis (linear static only)	Static, fatigue, thermal, and drop test analysis	Advanced FEA, CFD, impact, nonlinear, and multi-physics analysis
Applications	Simple parts, early-stage design validation	SMEs needing more robust simulations for product testing	High-end industries (aerospace, medical, automotive) requiring precise validation
Hardware requirements	Low: Runs on standard workstations	Moderate: requires mid-range computing power	High: needs high-performance computing

			resources
Cost	Included with SOLIDWORKS (free)	Additional cost – Mid-range pricing	Expensive: licensing and hardware costs can be high
Complexity of models	Simple	High to complex	Complex
Complexity of assemblies	Not suitable (Single part)	Complex assemblies with multiple parts	Complex assemblies with multiple parts
Confidence in results	Low	High	High
Potential to highlight design imperfections	Low	High	Moderate-High

Table 1: Evaluation matrix of various levels of simulation packages used.

In this study, we observed that using simulation packages for New Product Development in SMEs requires some considerations. Simulations may reduce the need for physical prototypes, cutting costs and speeding up the development cycle. The team used basic simulation quickly but efficiently after the initial training supplied by the FEA company and the partner Engineering University research team. The Engineers' experience/knowledge, along with basic simulations, can help identify potential failures, stress points, and inefficiencies early in the design process before investing in tools or production runs for regulatory testing. Digital testing allows designers to evaluate/test designs without requiring highly specialised engineers, contributing to their iterative design process, where rapid modifications and optimisations before manufacturing are highly valued. Subsequently, this enables SMEs to develop innovative, high-performance products that are more suited to navigate regulatory compliance challenges with higher confidence and fewer resources.

In contrast, without experienced simulation, results may be misinterpreted, leading to design flaws. Time-sensitive and complex projects may require high-fidelity simulations, and in consequence, need powerful hardware and some heavy investment to access premium or complete software packages. Therefore, it is necessary to restrict the time for properly evaluating basic packages or available software alternatives within the budget restrictions for SMEs.

6 CONCLUSIONS

Physical testing is costly, often requiring destructive prototype testing and expensive lab outsourcing. Failures can lead to tens of thousands of retesting costs. By integrating simulation and validation testing, iterative in-house optimization reduces risks before regulatory submission. Recent advancements in user-friendly software packages are making the integration of simulation tools into the industrial design process more accessible. Modern CAD-based simulation tools now offer streamlined workflows that allow non-experts, such as Industrial Designers, to conduct basic structural, thermal, and fluid analyses within familiar design environments. These tools reduce the technical barriers that previously hindered the adoption of simulation-driven design. The emergence of AI-driven generative design, automated simulations, and real-time optimisation can significantly reduce the time and expertise required to refine designs. As AI capabilities continue to evolve, they will further enhance simulation accessibility, efficiency, and predictive accuracy, making them a more practical and integral part of the iterative design process for both SMEs and large enterprises. The key limitations of basic simulation tools include the lack of advanced features and customizability found in more comprehensive simulation packages, not allowing users to define custom boundary conditions, thermal loads, or time-dependent forces, contact analysis, and fatigue studies. Users cannot generate detailed stress plots or animations beyond basic

visualizations. While SimulationXpress can provide quick insights during early design phases, it is not a substitute for more powerful tools like SolidWorks Simulation or third-party FEA software when dealing with complex or safety-critical engineering problems.

The industrial design team successfully implemented entry-level simulations in this study to reduce part costs and streamline development. Subsequent outputs enabled the refinement of design features with higher FOS and enabled the progression of the device to the regulatory pathway, where the SME invested significant funds and resources into the subsequent commercialization steps. This approach helped the company's regulatory team shorten the approval process by 3–6 months, addressing high-risk factors outlined in ISO:14971. While these tools offer valuable early-stage insights, they should complement, not replace, comprehensive premium simulations and feedback from an experience designer as they are essential for medical device development. However, for SMEs with limited resources and simpler devices, this framework can enhance confidence in design outputs before major investments, helping avoid costly failures and resubmissions. By leveraging these technological advancements, companies can more effectively integrate scientific methodologies into their design workflows, improving product performance, reducing development costs, and accelerating innovation.

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