Title:
Investigations of Low-cost Entry-level CAD Simulation for Virtual Regulatory Testing in Medical SMEs.

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Introduction:
While CAD simulation software offers significant benefits, such as improving product design, reducing prototyping costs, and speeding up development, Small to Medium Enterprises (SMEs) face several barriers to adopting these tools. 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 [5]. To overcome these hurdles, SMEs may consider starting with low-cost or less advanced simulation software, seeking training, or leveraging cloud-based solutions that reduce the need for heavy initial investment in hardware. Previous research suggested approaches to overcoming the challenges of integrating CAD packages in SMEs for product development [5], which can similarly be applied to simulation packages for medical devices.

Additionally, Medical SMEs face a range of challenges when investing in regulatory testing, from high costs, resource limitations, complexity, and uncertainty in evolving standards. SMEs may need to work with consultants, work with local labs, or seek external funding partnerships. Efficiently managing regulatory testing can be crucial to maintaining product quality, legal compliance, and market competitiveness. Collaborating with academia can assist in the refinement and selection of appropriate CAD packages with the required functions against standards that can be quantified in CAD and provide confidence in product outputs [13]. CAD can enable sensitivity analysis, various geometries and topologies, and aspects of CAD models that can be iterated and evaluated far more freely, enabling divergent and convergent design cycles to occur through digital technologies.

Problem definition:

Previous research explored the benefits of medical SME collaboration with academia for CAD packages and investigated the associated challenges [5]. Applying similar methods, the objective is to investigate ways to test and validate crucial mechanical design aspects with base simulation packages that are available. Regulatory testing is often conducted in approved test laboratories governed by notified bodies such as BSI. These approaches rely on designers to provide prototypes for testing that isn't guaranteed to pass. The team created a framework on how to navigate regulatory testing in a virtual environment, simulating specific regulatory tests in CAD to enable finite element analysis and provide high confidence in design outputs prior to a larger investment.

SolidWorks' low-cost, entry-level tools are evaluated to reduce steep learning curves associated with conventional simulation 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 qualitative metrics provided by simulation packages, where factor-of-safety (FOS) can be provided against stipulated test parameters in medical regulations, such as 60601-1 mechanical safety testing.

Regulatory testing:

Medical devices typically fail regulatory testing due to design-related faults. Mechanical engineers 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 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 for medical devices and how to navigate these within a 3D virtual environment to streamline the rigor of testing and reduce the resources required.

The medical design process is long, stringent, and expensive, with designers having to overcome a list of hurdles prior to sale on a market. Studies show that it takes 3-7 years to bring a device from concept to approval [8]. The average cost of bringing a class II device to market from concept to market is between $2-5 million [4]. Because medical devices are governed by a plethora of regulations where design and development can be a slow process to ensure compliance. The following standards are considered as some key medical device regulatory standards: BS-EN:60601-1, ISO:13485, IEC:14971 and IEC:62366 [10]. BS-EN:60601-1 is a critical step in the development of medical electrical equipment, ensuring that these devices meet essential safety and performance criteria. Passing these tests is necessary for regulatory approval and market acceptance, and safeguards both patients and healthcare providers [11].

CAD Simulation packages:

CAD simulation packages are heavily utilized for design validation, including the surveying of Quality assurance and testing tools [3]. The use of CAD packages and simulation tools is heavily evaluated, particularly in academia [6], detailing various tools, practices, and approaches [1]. Sufficient evidence suggests a need to integrate regulatory-based simulation [9], and various research is exploring applications of computational modelling and simulation for medical devices, such as product lifecycle assessment [2] and for advancing regulatory science for medical devices in FDA laboratories [12].

Many suitable software programs exist for CAD simulation, and studies evidence thorough cross-examination for various applications [7]. SolidWorks was used to navigate complex regulatory testing in the CAD environment, showing how to formally frame the CAD evaluation tasks within regulatory insights to translate a practical field of mechanical engineering to a virtual environment. Design for regulatory compliance is a rare skillset and navigating regulatory requirements, testing outputs and securing and maintain certification can be an extremely costly, resource intensive and complex battle. When evaluating CAD tools, there are several sub-divisions that could be considered. Premium gold standard packages such as SiemensNX, Creo or CATIA, mid-level standard software's such as SolidWorks and Autodesk packages and the low-band AutoCAD, Inventor. Other standalone packages exist such as Simul8, though these won't be evaluated.

Methodology:

BS-EN:60601-1 is the chosen regulation applied to the FEA studies. Section 15.3.2, Mechanical strength Push tests, will provide the specific classification and test parametrization for the virtual protocol. Other mechanical strength tests defined by BSI, will be evaluated by the research teams using the framework presented to assist others how to formally define these tasks virtually with CAD simulation environments for pre-regulatory testing and design validation. The following framework (Fig.1) has

been developed to assist in navigating regulatory testing through CAD for the medical design process. Comprised of 5 main steps, each core section has separate sub-steps that progress through scoping, defining tests, integration into CAD, evaluation, and transfer.

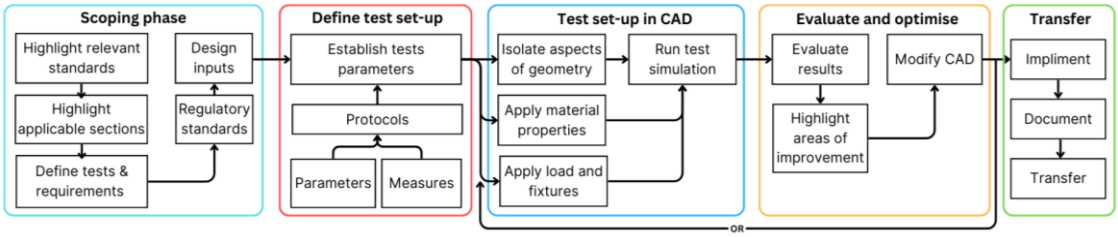

Fig. 1: Framework for navigating regulatory testing through CAD.

Regulatory testing ensures the safety of the devices being developed, against a risk assessment in accordance with ISO:14971. When evaluating the design, the interpretation and anticipation of potential weaknesses in the design should help navigate the appropriate applications of the test parameters. Ventilation grills are typically evaluated more in the design process as they 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 the exposure of electrical components. When a device is sent off for regulatory testing, a laboratory will use certified equipment designed to test against the details provided 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 the following task:

'External parts of an ENCLOSURE are subject to a steady force of 250 N ± 10 N for a period of 5s, applied by means of a suitable test tool providing contact over a circular plane surface 30 mm in diameter. However, this test is not applied to the bottom of an ENCLOSURE of ME EQUIPMENT having a mass of more than 18 kg'.

For this study, SolidWorks is selected as an industry standard CAD package with free simulation tools such as SimulationXpress. Successful implementation into these entry-level tools will likely evidence transferability to other software. Using CAD for the design of the enclosure can enable iterative development of finite aspects, such as ventilation, which is often a weak point. A vent grill design is iterated and tested in SolidWorks to evaluate the optimal airflow-to-strength ratio, ensuring maximum surface area for airflow without compromising the FOS results in the FEA testing. The designs were evaluated by determining the cooling capacity of the condenser for which the vents were designed.

Results:

Though 10 vent iterations were evaluated in the larger study, 3 versions are evident. Prior to designing, the airflow against a vapor 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 an HVAC system. From these conditions, various vent grill options were designed in SolidWorks and simulated for stress testing conditions. Figure 2 illustrates the 3 most suitable iterations selected for testing.

The definitions for the test's conditions used a pre-determined moulding material, force applied in Newtons, force calculation using Poisson's Ratio (0.394), and definition of the fixings. Following this, a deformation scale and Factor of Safety is provided, where the team evaluated an ideal output of 3< FOS. This would provide high enough confidence levels against the risk assessment with ISO:14971 to progress. Using the specific extracts from the standards in the scoping phase can provide protocols that can inform the virtual test environment, material, loads, and more. Fig. 3 below illustrates the test

parameters used, where a specified load of 30N is applied to various locations on a vent grill. Fig 3 below illustrates where the simulations were conducted on the given vents for repeat testing. Locations were selected based on perceived weakest points, based on minimal potential surface contact against the test equipment, resulting in maximum force to minimum surface distribution.

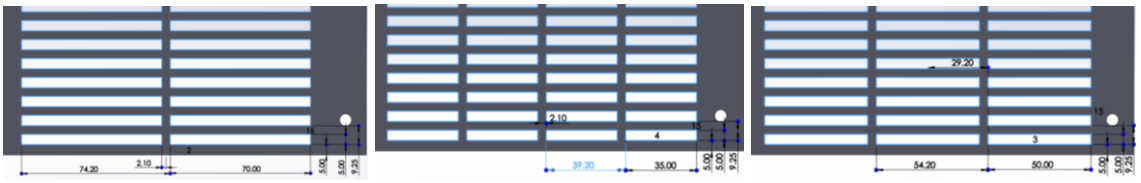

Fig. 2: Vent grill options, optimized in the design process.

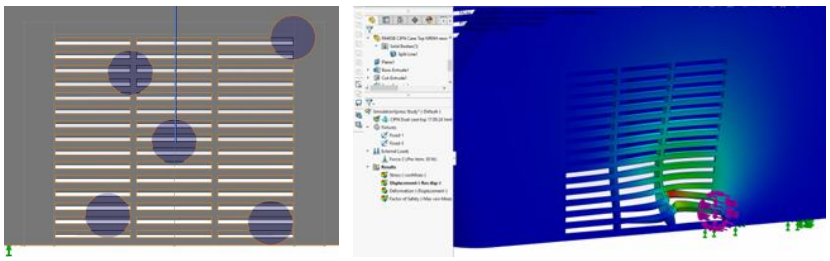

Fig. 3: Defining test parameters in SimulationXpress against BS-EN:60601-1 Push Test.

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.

Conclusions:

The base functions of simulationXpress provides limitations that do not permit for thorough analysis, though various finite elements can be explored that are low complexity. This abstract explored an example where a specific test in a medical device regulation could be navigated using FEA in the low-cost entry-level SimulationXpress package from SolidWorks. The team explored a handful of further specific tests during this project that isolated aspects of potential failure in a medical device enclosure. This enabled virtual iteration that provided early validation and high confidence levels capable of producing a commercial mould for a medical device enclosure that has been submitted for BS-EN:60601-1 testing. Further testing includes 15.3.1 General, 15.3.3 Impact test, 15.3.4 Drop test, 15.3.6 Mould stress test and more. Comparatively, these tests are physical and resource intensive, often including destruction testing of expensive small batch prototypes, use of expensive technical test equipment and outsourcing in a lab one-off payment to test facilities. Though these costs are inevitable and necessary, sometimes they cost >10's of thousands of pounds and if you fail, you must resubmit and pay again. To avoid this aspect, technical simulation and validation testing can enable iterative optimization in-house prior to shifting to the regulatory path. In this research team is highlighting aspects of mechanical strength testing according to IEC:60601-1.

The team has experience with other more comprehensive CAD Simulation packages and has attributed the use of these entry-level tools in this test to reducing part costs and streamlining the development process. The company's regulatory team were able to reduce the regulatory path by 3-6 months from these evaluations, mitigating high risk aspects against the risk register stipulated by ISO:14971. Readers should be aware that these approaches should not replace thorough,

comprehensive approaches available through premium functionalities, which are essential for medical device development. However, for SMEs with limited resources and simpler devices, this framework can assist in building confidence in outputs prior to investment to prevent failures and resubmission.

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