

Bringing Innovative Medical Products to Market Faster

SUMMARY

To succeed in today's medical device manufacturing industry, product designers must not only create innovative medical products but also navigate an increasingly challenging regulatory environment. SolidWorks® Office Premium software can help you meet this challenge. Powerful part definition and industrial design tools foster product innovation while integrated software prototyping and comprehensive design management capabilities support regulatory compliance. With SolidWorks software, you can quickly develop and analyze medical devices and components – and bring them to market faster.



Today, medical equipment manufacturers face increasingly demanding regulatory requirements that raise the costs and risks of product development. Stringent federal Food and Drug Administration (FDA) regulations require careful and comprehensive documentation of your work, such as maintaining a design history file with the analysis results that provided the basis for a particular design decision. This exacting regulatory environment increases the probability of unsuccessful product trials, which can put return on development costs at greater risk.

To manage product development risk, many medical device manufacturers are moving away from high-end point solutions for design, analysis, and product data management (PDM) and toward integrated product development platforms that address all of these functions. This approach can increase the chances for success because it accelerates validation of innovative design concepts and automates design documentation, providing you with the flexibility and agility you need to comply with regulatory requirements and counter increased risk.

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Success in today's challenging environment requires a faster process of innovation with shorter design and validation cycles that reduce both time-to-market and engineering costs. You can greatly reduce build-and-test cycles by quickly analyzing the performance of many design concepts in software, then separating out the viable concepts for further testing, trials, and development. Using integrated design analysis tools, you can more efficiently evaluate the performance of a design under a wide range of usage, handling, and storage scenarios, such as determining what will happen when a surgeon drops a surgical instrument on the floor, during early conceptual design.

Many relatively small medical device companies cannot easily afford the high cost of providing the people and infrastructure needed to support high-end design and analysis tools. Yet these companies still need to increase their industrial design and analysis capabilities in order to compete successfully against the increasing number of medical products sold directly to consumers.

SolidWorks Office Premium software can help you meet these challenges by delivering a complete, easy-to-use, and simple-to-administer solution. With SolidWorks software, you have the necessary core product definition, collaboration, manufacturing, and documentation tools to beat competitors to market. In addition, a wide range of powerful, integrated analysis capabilities allow you to evaluate the performance of your design concepts as you create them. Whether you need to evaluate fluid flow, mechanical stresses, or the effects of temperature, SolidWorks Office Premium enables you to analyze designs quickly without ever leaving your familiar modeling environment.

By utilizing the assembly and component configuration management capabilities in SolidWorks Office Premium software, you can develop and manage families of assemblies and parts with different dimensions, materials, capacities, and other properties. SolidWorks software makes it easy to manage the decision-making process. You can store and track each version of a design along with the analysis results and other details that document the engineering decision-making process. With SolidWorks software, you also have the necessary surfacing capabilities for developing a modern, flowing style that is as visually appealing as it is functional.

Product Definition and Conceptual Design

Core capabilities include sophisticated solid modeling features, such as lofts, variable-radius fillets, shells, and draft angles.

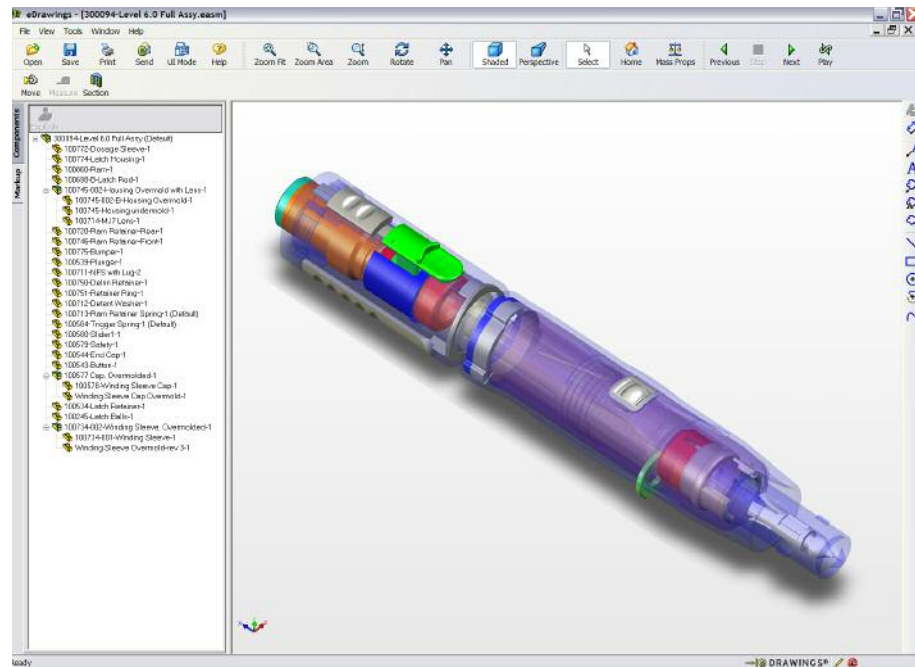
Using SolidWorks software, you can easily create a feature-based parametric model of your design concept that captures all the information needed to define the product, as well as manage the change and documentation process. Core capabilities include sophisticated solid modeling features, such as lofts, variable-radius fillets, shells, and draft angles. You may need access to these features in order to define the geometry, function, and manufacturability of complex medical devices. With the ability to visualize designs in 3D, you can identify potential problems before investing additional money in the product development process.

Within the same interface and file format, SolidWorks software also provides surface modeling features to help define the flowing, sweeping surfaces that you need to deliver a cutting-edge industrial design. For example, the Fill feature offers an n-sided surface path that allows you to fill in a surface patch tangent to a space defined by any number of boundaries. You can also sketch a network of curves and pull any point in a curve to modify the surface, as well as combine both analytical entities and splines into a single feature.

With PhotoWorks™ software, you have the ability to create photorealistic images that rival those produced with more expensive software tools. The SolidWorks Animator tool goes a step further by helping you create animations from parts and assembly models easily. You can also use this tool to capture assembly motion and demonstrate how the moving parts of the medical device operate.

A significant portion of a typical medical device consists primarily of purchased components, such as semiconductors, circuit boards, display screens, valves, and pumps. For each project, you often need to remodel these purchased and commonly used components. SolidWorks software can help you overcome this problem with the help of the Design Library – a central location where you can access a wide range of standard, vendor-specific, and internal company design libraries of finished models. You can use the Design Library to add new parts to a product or assembly simply by dragging and dropping them into the design.

The eDrawings™ email-based collaboration tool allows you to further streamline the product definition process by improving communication with managers, marketers, customers, and vendors. You can deliver 2D drawings and 3D models to non-CAD users who can view, print, and review them with free viewer software, and then provide feedback through intuitive markup tools. With eDrawings, everyone who has valuable feedback and input to offer during the product definition and conceptual design phase can directly interact with the design by panning, rotating, and zooming in and out to view the model from any angle. They can even view animations of the medical device in operation so they fully understand how the product works. This high level of access and insight improves the quality of feedback and input that the design team provides provide early in the product development process.



With the eDrawings tool, you can communicate your design concepts quickly and easily to everyone involved in the design process.

Product Design on an Integrated Platform

Having the ability to manage multiple configurations from a single document makes it easy to apply changes to all of your configurations or to just those that you select.

SolidWorks Office Premium software automates product design, makes it easy for you to take a design from concept to prototype, and documents every step along the way. Working on an integrated design platform will help you to reduce repetitive design tasks substantially, access analysis capabilities within the same environment easily, and create comprehensive design documentation automatically.

Using configuration management capabilities, you can enter dimensional parameters in a spreadsheet and use a design table to automate the creation of hundreds of part or assembly iterations in seconds. You can turn features on or off in different configurations and can assign properties – such as material, part name, and cost – to a configuration. Having the ability to manage multiple configurations from a single document makes it easy to apply changes to all of your configurations or to just those that you select. With these capabilities, you can greatly reduce the amount of work required and time spent to produce and maintain a family of products based on a single technology platform.

Having solid modeling and design analysis (finite element analysis, or FEA) integrated within a single environment, means you can evaluate design performance at a much earlier stage, as well as the results used to refine and optimize the design, rather than performing these tasks as a final validation check prior to prototyping and production. You can use COSMOSWorks® Designer software,

which is included with SolidWorks Office Premium, to determine the stress, strain, deformed shape, and displacement of components under operational loads. This tool allows you to identify problems quickly and inexpensively and then modify your design to address them. The Drop Test feature in COSMOSWorks software allows you to determine the effect of impact on the proposed design when someone drops it from various heights. Recently, a company used COSMOSWorks software to evaluate a concept for a needle-free injection system, using integrated analysis to determine the contact pressure and safety factor.

COSMOSFloWorks™ computational fluid dynamics (CFD) software simulates the flow of liquids and gases through and around a product, while calculating the flow velocity, pressure, temperature, and other relevant variables. Using this tool, a medical device manufacturer evaluated alternative heart valve designs to determine the turbulence of flow, pressure loss, and overall back pressure in the valve. Another company used COSMOSFloWorks software to analyze the oxygen flow concentration from the mouthpiece of an oxygen headset system.

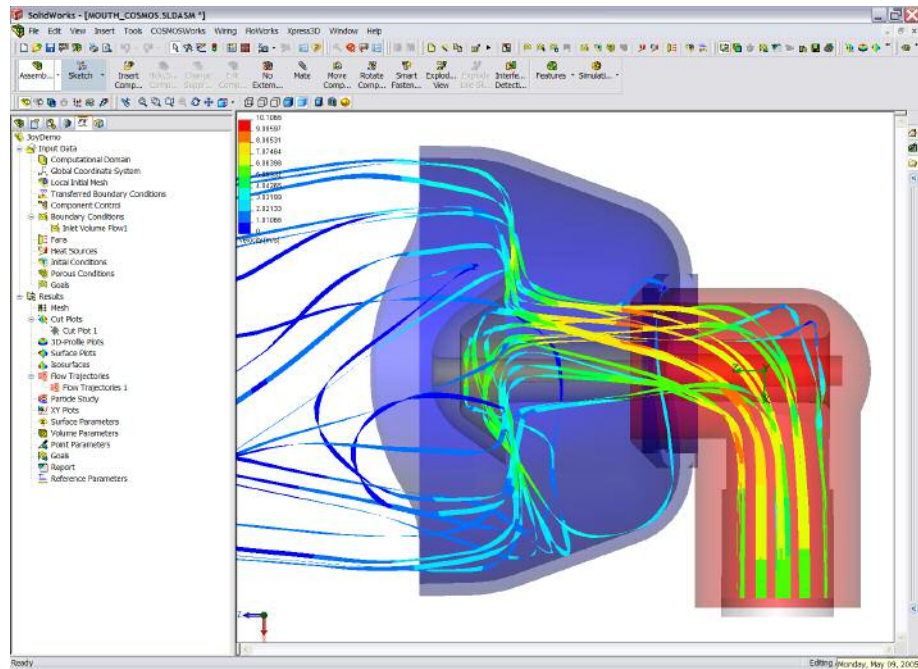
Another application within SolidWorks Office Premium, SolidWorks Routing software, helps you route wiring harnesses in closely packed medical device enclosures. With the SolidWorks Routing tool, you can import electronic design automation (EDA) data to determine the number and size of wires and cables, as well as other information. Whenever the electronic design changes, new data can be imported to drive the resizing of electrical routes within the product.

SolidWorks Office Premium software includes powerful and intuitive tools for creating enclosures and other sheetmetal components for medical devices in folded or flat states. The software automatically applies all sheet-metal properties, such as metal thickness, bend radius, and bend relief, and automates the creation of flanges, tabs, lofted bends, flat patterns, normal cuts, corner cuts, normal treatments, hems, jogs, and more.

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After you have used this integrated platform to refine and optimize your design, you can automatically generate design documentation in the form of production-level 2D drawings from your 3D assembly model. By just drawing a line, you can generate section views. SolidWorks software will section the assembly and create the drawing view automatically. You can quickly create exploded views to describe how to operate and maintain the device from your 3D model by selecting sections to define 2D detailed drawing views. You can also easily annotate these views with balloons keyed to your bill of materials, thereby highlighting the components of interest. The 2D drawings and 3D model are bidirectionally associated, so that any changes made to one will instantly update all others.

Prototyping and Testing



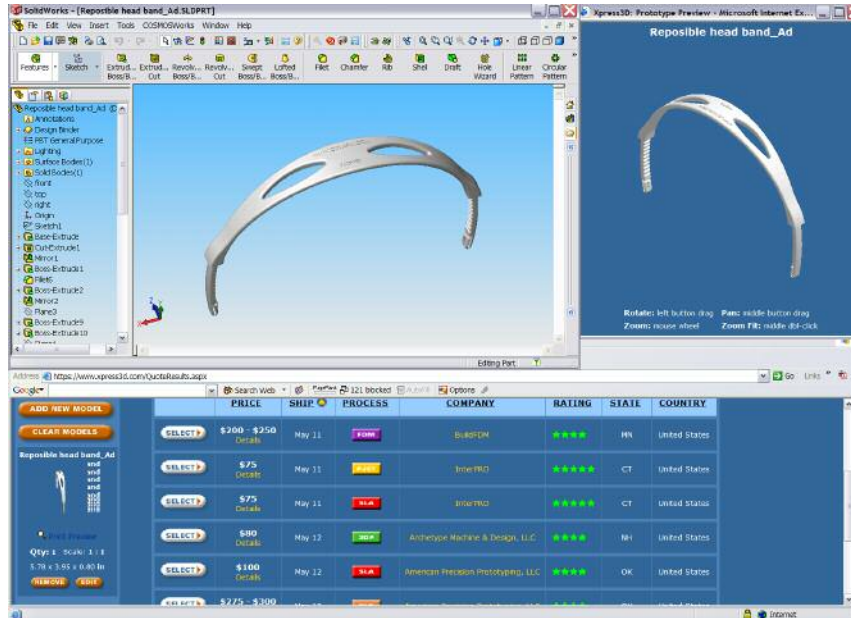
COSMOSFloWorks enabled engineers to determine the optimal design for a new oxygen delivery device.

The SolidWorks Print3D web portal gives you immediate access to the most effective rapid prototyping technologies in the industry...

Although advances in display technology have substantially improved its visual prototyping potential, working with an actual physical prototype is still the most intuitive means for reviewing a design. Prototyping and testing prior to trials is also an FDA requirement, and medical product developers need access to the latest rapid prototyping technologies to keep development on track. The SolidWorks Print3D web portal gives you immediate access to the most effective rapid prototyping technologies in the industry, including stereolithography (SLA), fused deposition modeling (FDM), selective laser sintering, rapid injection molding, and 3D printing. By automating prototype development, SolidWorks Print3D enables you to order prototypes in minutes instead of hours.

Engineering changes typically occur at a rapid rate during the product assembly and testing phase. SolidWorks software helps you avoid costly mistakes by ensuring that changes made anywhere in the process automatically update all product documentation, including parts, assemblies, and drawings.

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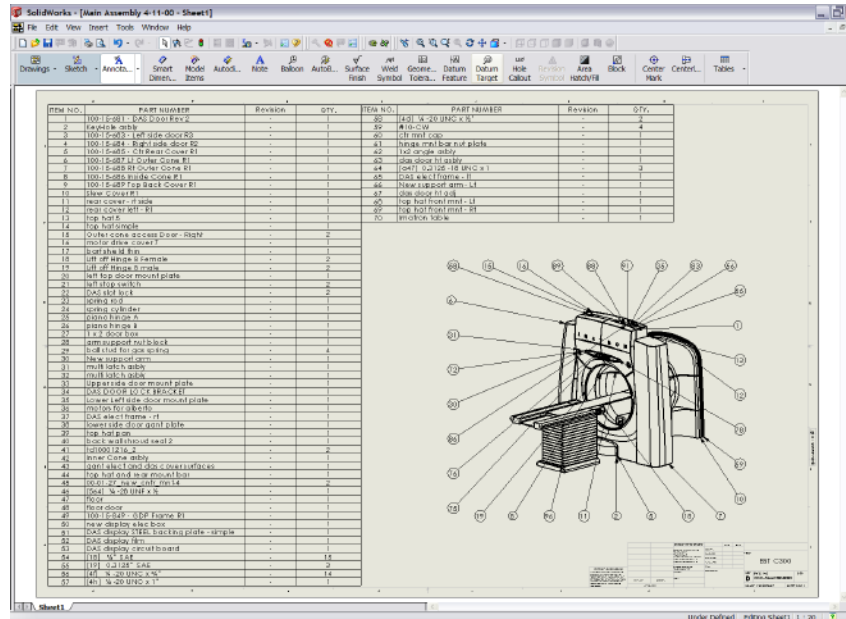
Manufacturing

SolidWorks software automatically maintains your bill of materials, so you can export it as an Excel spreadsheet or in other formats for use with material requirements planning (MRP) systems.

Once you have generated, prototyped, and tested your design, SolidWorks Office Premium software automates production setup and manufacturing. SolidWorks software automatically maintains your bill of materials, so you can export it as an Excel spreadsheet or in other formats for use with material requirements planning (MRP) systems. This information will help you save time and avoid errors during the purchasing process. The software tracks a wide range of information, such as the manufacturer of purchased components, model number, size, and weight. By generating a single bill of materials for multiple projects with numerous parts, quantities, and configurations, you can speed the transition to manufacturing and can purchase greater quantities at lower prices.

SolidWorks Corporation partners with industry-leading computer-aided manufacturing (CAM) software companies to deliver a variety of powerful CNC programming solutions for milling, turning, and electronic discharge machining. Since Certified CAM Solutions read native SolidWorks geometry and are fully associative, your design changes are reflected in the CNC program. Certified Gold Solutions also provide single-window integration with the SolidWorks model, enabling generation of the CNC program path within the familiar SolidWorks environment.

The SolidWorks Manufacturing Network simplifies the process of finding design and manufacturing service providers that use SolidWorks software. By working with native SolidWorks files, you do not have to worry about converting or re-creating files. You can easily find the right supplier on the network by browsing through any of 21 different categories, such as metalworking, machining, injection molding, and sheet-metal fabrication, or by simply searching on keywords.



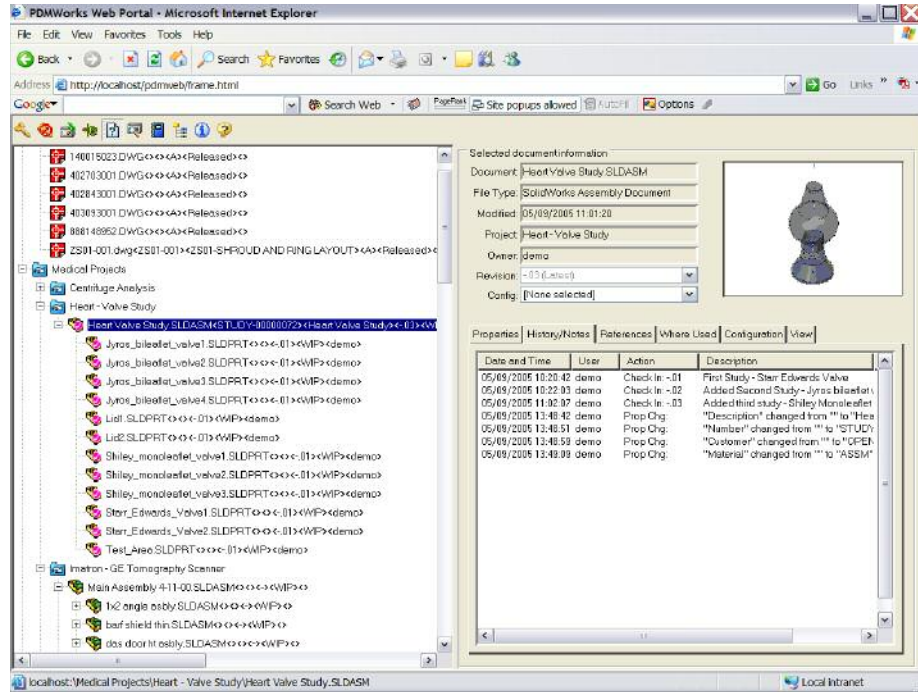
With SolidWorks software, you can automatically generate a bill of materials, which you can export as an Excel spreadsheet or in other formats for import into MRP systems.

Regulatory Documentation Compliance

Instead of incurring the time and expense required to manage, archive, and track design documentation in either a manual, paper-based or high-end revision control system, you can cost-effectively automate the documentation function with SolidWorks Office Premium software. The SolidWorks Office Premium development environment includes PDMWorks® software, an integrated product data management (PDM) solution that securely archives and organizes multiple versions of previous projects. With PDMWorks, you can maintain a high level of control and manage the information needed for your medical product design without resorting to an expensive, hard-to-administer, high-end infrastructure. PDMWorks helps you manage, track, and document the engineering change process throughout the product development lifecycle. With PDMWorks, you can document the reasons for making design

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decisions, including analysis and test results, and can track revisions generated at each step of the process. PDMWorks delivers more flexibility than many competitive version control systems, so you can define relevant version and revision schemes.

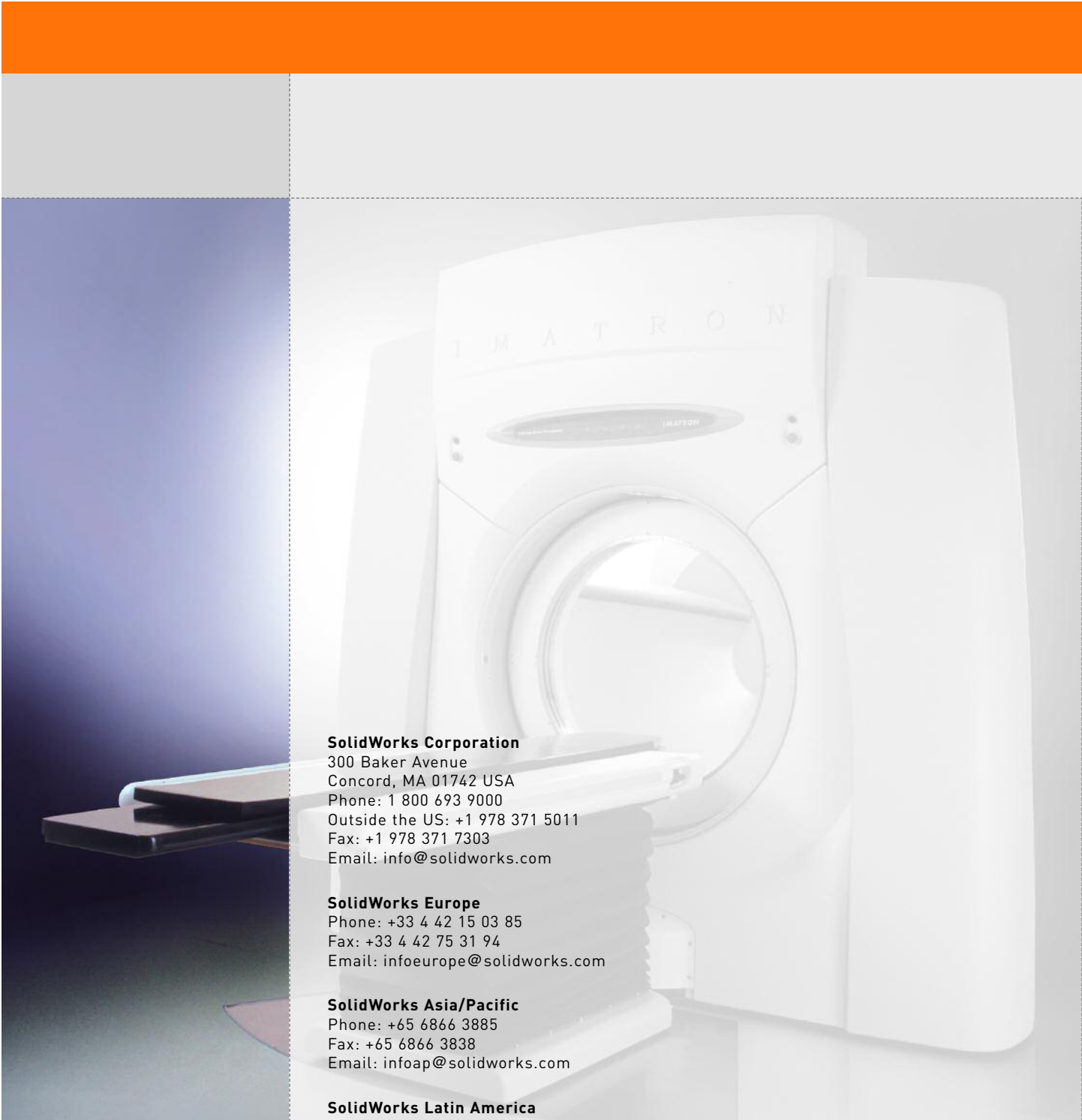


PDMWorks manages design revisions and automatically captures the history of all revisions.

CONCLUSION

The regulatory and competitive challenges facing medical device manufacturers today are tremendous – but so are the opportunities. SolidWorks software can help you meet the challenges and maximize the opportunities, while also reducing your initial investment and ongoing expenses. SolidWorks Office Premium software provides you with a full range of solid modeling and surfacing tools for designing geometrically complex and stylish medical devices – and turning them into functional, manufacturable products. With powerful, integrated SolidWorks design visualization and analysis tools in hand, you can evaluate the performance of alternate design concepts long before building physical prototypes.

Robust collaboration, automated rapid prototyping, and integrated manufacturing applications can help you bring validated designs to market faster than the competition. The integrated SolidWorks Office Premium environment can help you design more innovative medical devices faster and at less risk while at the same time providing you with the data management and version control tools you need to document your design process from start to finish, ensuring that your design complies with all applicable regulatory requirements.



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