

2008 Highlights

- Hired 10 additional engineers who have added unique skills to our team
- Added FEA and CFD services for potential time and cost savings
- Acquired an additional 5,000 square feet to support our growth
- Anticipating ISO 13485 approval next year

Did you notice our new look and logo? The updated design not only gives us a consistent look, but also represents the many exciting and challenging components of a design process.

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Growth by design

Employees, customers are at the core of our success

Greetings!

It's been an exciting time of growth over the last four-and-a-half years, and thanks go out to our existing and expanding customer-employee base.

We're excited to announce that we are expanding our space by an additional 5,000 square feet (15,000 total) to support our anticipated growth over the next few years.

Much of our work over the last four years has been devoted to improving internal processes and systems so we can provide a premier level of service to our customers. Although each incremental improvement has been great, we expect the efforts to come to fruition next year with an ISO 13485 approval.

Recent projects

While our customer and project mix is quite diverse in the medical field, we have recently had some great opportunities to tackle an interesting array of orthopedic projects including spinal implants and trauma devices.

Other innovative projects include the development of unique electronics and soft-

ware systems for respiratory therapy devices, wireless sensors and mobile diagnostic devices.

Our employees

Over the past year we have hired 10 additional engineers in all disciplines (EE, ME, SW, BME) and degree levels (PhDs, Masters, Bachelors). The additions have allowed us to bring unique skills to our team including micro-fluidics and the field of thermal sciences. With new staff, we can now offer Finite Element Analysis (FEA) and Computational Field Dynamics (CFD) services. (More about that on page 3).

The secret ...

... to our success is directly tied to the fact that we sincerely care about how we service our customers, and how we value our employees. We believe in working hard for our customers, delivering value and taking the extra steps necessary to help our customers meet their overall business objectives.

Our staff is passionate not only about the development of medical technology, but also about customer service.



Peter DeLange
President and CEO

Looking ahead

Over the next year, we will continue to focus on the science and engineering side of medical device development while expanding our service offerings.

We expect to hire 8-10 additional employees over the next 12-18 months, which will add depth in each engineering discipline, fill out openings in our quality group and allow us to staff up for a few new, high-tech medical device offerings.

We are looking forward to a great 2009 for our customers, some of which have significant events on the horizon including regulatory approvals, product launches, funding and even a possible exit!

Upcoming Events



September 23-25, 2008

*Donald E. Stephens
Convention Center
Rosemont (Chicago), IL*

Devicix will have a booth at the first ever MD&M Midwest event where there will be an opportunity to connect with more than 40,000 medical OEM professionals.

October 22-23, 2008

*Minneapolis Convention Center
Minneapolis, MN*

Devicix will again have a booth at the Twin Cities' premier event for medical design and manufacturing. The event will include 650 leading suppliers of the software, raw materials, manufacturing equipment, components, and contract services used to design and produce medical devices.



December 10, 2008

*Minneapolis Convention Center
Minneapolis, MN*

For the second year, Devicix will sponsor the Cyber Café located in the lobby area at the entrance to the Expo near the bottom of the

escalator—booth 3144. In addition to the informational booth, Devicix will offer attendees free access to the Internet.

February 10-12, 2009

*Anaheim Convention Center
Anaheim, CA*

Devicix will have a booth at this event, which is the world's largest event for medical design and manufacturing.



September 2-6, 2009

*Hilton Minneapolis
Minneapolis, MN*

The theme of the 31st Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC) will be "Engineering the Future of Biomedicine." The event

will include a broad spectrum of topics from biomedical engineering and physics to medical and clinical applications. More information is available at www.embc09.org.



Have you heard?

Peter DeLange (President and CEO) gave an invited lecture at BioNova in early 2008 about the commercialization of medical devices in the United States, as well as the Minnesota climate for medical devices. Peter attended the event in Halifax, Nova Scotia, as a guest of the Consulate General of Canada. Peter is also serving on the board of the University of Minnesota's Institute of Engineering and Medicine.

Raymond Lei, MS (Software Engineer) is serving as an instructor this fall for the digital signal processing lab at the University of St. Thomas.

The Biomedical Engineering Society selected **Jon Moon, PhD** (CTO) to be a Program Evaluator under the Engineering Accreditation Commission of ABET. Dr Moon was also appointed Chair of the Industry Relations and Professional Activities Committee of the IEEE Engineering in Medicine and Biology Society and to the advisory board of the University of Minnesota Department of Biomedical Engineering.

Andy Pfahnl, ScD (Engineering Management) will serve as an advisor to the University of Minnesota's Biomedical Engineering Senior Design Class during the 2008-2009 school year. This course simulates real-world engineering development. Dr. Pfahnl will guide students in a project to quickly determine tracheal tube position. Dr. Moon served as the advisor from Devicix during the 2007-2008 and 2005-2006 school years. Devicix is happy to provide this service to the University and has also hired students through the course.

Taking the green challenge

By Jon Moon, PhD

It's not easy being green – especially when renting space in a suburban industrial park. Last year Devicix moved to Eden Prairie to reduce travel distance for employees and clients. Devicix is doing what we can to help the environment.



We collect and recycle all paper, cardboard, bottles, cans and plastic bags. Employees re-use paper in our scratch printer.

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FEA and CFD numerical testing is now available

To enhance its product development process and further save customers time and money, Devicix now offers Finite Element Analysis (FEA) and Computational Fluid Dynamics (CFD) analysis capabilities. These numerical analysis tools are effective in determining the mechanical, thermal and fluid flow characteristics of a medical product design.

FEA is used to assess the feasibility and functional capabilities of designs by calculating their stresses and strains when subject to particular loads and boundary conditions. These types of analyses are heavily leveraged in the development of surgical devices including implants, delivery instruments, disposable components and applicators. The software Devicix uses for these analyses allows for static and dynamic analyses as well as linear and non-linear analyses, which are particularly useful for designs that incorporate Nitinol.

CFD analyses on the other hand are used to characterize fluid systems allowing the determination of pressure losses, fluid flow rates, and detail velocity distributions. The software allows existing 3-D geometry to be directly imported speeding this analysis process. Typical applications include fluid dispensers and electro-mechanical systems such as Continuous Positive Airway Pressure (CPAP) machines.

“From a development and cost perspective, it’s cheaper and faster to run numerical experiments than prototype experiments,” said Devicix Engineering Manager Andreas Pfahnl. “The version of the design you end up prototyping often requires fewer refinements which translates to overall project cost savings, and you have an overall better understanding of the expected performance and behavior of the design.”



For example, the FDA typically requires specific experimental testing of implantable devices. By using FEA, an implant design can be exercised through those same tests on the computer and the design refined in advance of submitting the prototype.

The first step of a numerical analysis involves taking the solid model and preparing it so that it can be analyzed.

“From a development and cost perspective, it’s cheaper and faster to run numerical experiments than prototype experiments.”

Features and fine details that have little effect on the results are removed to optimize the mesh size and solve time. Loads and boundary conditions are then applied, and finally the model is meshed and the simulation started. The solve time for simple models ranges from a few minutes up to 15 minutes, while more complex flow analyses or large-displacement mechanical analyses require more. The last step is post processing, which involves extracting and presenting the data. With FEA, failure criteria are compared against resulting stresses and strains (displacements), and for CFD most often velocity and pressure profiles are examined.

“By offering FEA and CFD analysis services, our customers avoid the associated equipment, software and user training costs,” said Pfahnl. “This is a valuable service that we’re excited to offer to our client base.”

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We changed to timer thermostats that dramatically reduce energy use on weekends and at night, and we work hard to make sure lights are turned off.

Whenever possible we wash dishes instead of using styrene utensils or throw-away plates and cups. We built a shower-changing room to make commuting by bike as easy as possible. The company also signed up for the Wind Energy Pro-

gram from Excel Energy. We even drink tap water.

Next year we plan to be even greener and look forward to working with other companies, community groups and local government.

Pedaling for MS



Six members of the Devicix team took the MS150 bike challenge June 6-8 and raised \$2,000 to support research and treatments for Multiple Sclerosis.

Pictured (from left to right) Kody DeLange, General Manager Dee DeLange, CEO Peter DeLange, Medical Engineer David Jansen, Business Development Manager Rick Stein and Biomedical Engineer Patrick Corneille.



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About Devicix

Devicix is a multi-disciplinary engineering firm focused on helping medical device manufacturers design and deliver new products to market in an accelerated time frame.

The Devicix design team includes electrical, mechanical, computer science, biomedical and computer engineers, as well as an on-staff PhD. This team has a proven track record of designing and developing innovative medical devices on an accelerated time schedule.

Spotlight on ...



Mechanical Engineering

By Andy Pfahnl, ScD

The Devicix mechanical engineering staff includes eight experienced, professional men and women supporting the development of a variety of medical products ranging from disposable and implantable components to electro-mechanical systems covering Class 1, 2 and 3 devices.

The staff supports a variety of different client needs. Most involve developing products from concept through production readiness including helping with FDA-related qualification testing. Some projects are more limited in scope and may only involve developing a prototype or proof-of-concept of an invention. In other cases, the projects are on-going

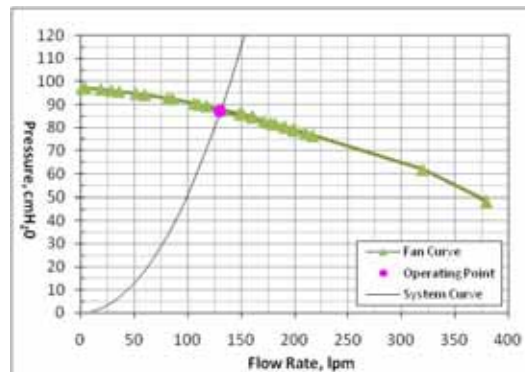
in that Devicix provides a flexible source of design and engineering capacity for a new product or sustaining engineering work (e.g. drafting, design and modeling, failure analysis, etc).

Devicix staff members are degreed mechanical and biomedical engineers that often are part of a larger technical project team of controls, software and electrical engineers. The skill sets and backgrounds are well rounded to cover key disciplines necessary for medical products, including:

- **Mechanics and kinematics** to assess static and dynamic loads. Material considerations are important for cost,

weight and manufacturability. FEA tools are often leveraged.

- **Fluids systems** to determine flow and pressure characteristics. Flow network models are often developed and CFD analyses undertaken to evaluate the contribution of each component in the overall system performance.
- **Heat Transfer** to control temperatures of components or fluids, and has involved design of custom heaters and temperature controllers to optimize cost and reduce size over off-the-shelf parts. Numerical tools are often leveraged to analyze complex geometries and assemblies.



- **Packaging** which refers to how all the components of a product are assembled in a design, and also how a product is shipped and stored. Sterility requirements are an important consideration.

- **Industrial design** which includes ergonomics and aesthetics, development of surgical instruments and consumer products, incorporates many human factors.

Devicix has laboratory facilities to support the mechanical engineering tasks with a variety of test and measurement equipment, a wet lab, a fabrication shop, and space for pre-production manufacturing. The experience of the staff, together with a proven product development process, ensures other aspects are not overlooked such as manufacturability, and regulatory and safety requirements.