



NANO ECHO AB IMPROVING EFFICIENCY AND REGULATORY COMPLIANCE IN DEVELOPING RECTAL CANCER DIAGNOSTIC DEVICE WITH 3DEXPERIENCE WORKS SOLUTIONS

Case Study



NanoECHO relies on design, collaboration, communication, and data management solutions from the **3DEXPERIENCE** Works portfolio to accelerate development of its rectal cancer diagnostic imaging device while also satisfying regulatory data and revision control requirements.

Challenge:

Develop a new and improved rectal cancer diagnostic device that utilizes the company's patented magnetomotive ultrasound technology to help differentiate between diseased and healthy tissue, and ensure traceability and regulatory compliance during the development process.

Solution:

Leverage SOLIDWORKS design and SOLIDWORKS CAM machining software in conjunction with solutions from the 3DEXPERIENCE Works portfolio—including Collaborative Designer for SOLIDWORKS, Collaborative Industry Innovator, and Collaborative Business Innovator—on the cloud-based 3DEXPERIENCE platform.

Results:

- Realized more efficient development process with high traceability
- Satisfied revision control regulatory requirements for medical devices
- Saved time and money via cloud-based product data management (PDM)
- Innovated improved rectal cancer diagnostic device

NanoEcho is developing a new technology for a rectal cancer diagnostic device with higher precision, making it possible to customize treatment for each individual. The imaging technology is based on a new diagnostic method called magnetomotive ultrasound, which combines magnetism with nanotechnology and ultrasound technology. Iron oxide nanoparticles are put in motion by a magnet within the device and are used as the contrast agent with ultrasound technology to show whether cancer has spread to the rectal lymph nodes or not, an important marker of how far a cancer has progressed.

The NanoEcho images are intended to facilitate the differentiation between diseased and healthy tissue, and at the same time determine the location of the cancerous tissue more precisely. The goal is to be able to provide a more accurate and cost-effective diagnosis of cancerous diseases. With clearer diagnostics, doctors receive better guidance for a more individualized treatment plan, improving a patient's quality of life after treatment, increasing the chances of survival, and reducing treatment costs.

NanoEcho was founded in Lund, Sweden, in 2015. The company began a clinical development study at Sahlgrenska University Hospital in 2021, and an additional clinical development study is planned to start at Skåne University Hospital in Malmö in 2022. Part of the company's business strategy is to quickly



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— Daniel Skagmo, Lead Hardware Engineer

develop the NanoEcho device to be first to market with its device despite the regulatory challenges involved with developing and commercializing a medical device. To achieve its ambitious development goals, NanoEcho needed a 3D design solution as well as a product data management (PDM) system to satisfy regulatory requirements for document control.

According to Lead Hardware Engineer Daniel Skagmo, the company began development using SOLIDWORKS® 3D design software. "At NanoEcho, we have high demand for quality and efficiency and needed a powerful development system that was ready to use with low maintenance requirements," Skagmo explains. That's why the company implemented SOLIDWORKS.

To support development, NanoEcho needed a flexible way to address the company's regulatory challenges without IT overhead. "One of the biggest challenges we have is the regulatory demand on the development of this type of novel medical device," notes CEO Dr. Linda Persson. "For market approval, we need both technical, biological, and clinical verifications and validations, with strict tracking of changes and document control."

By late 2021, NanoEcho had learned from SolidEngineer AB, its SOLIDWORKS reseller, about design, collaboration, communication, and data management solutions from the 3DEXPERIENCE® Works portfolio. The innovation portfolio, purpose-built for the mainstream market, leverages the cloud-based 3DEXPERIENCE platform to connect a business' ecosystem in a single, unified, collaborative environment. These solutions—including Collaborative Designer for SOLIDWORKS, Collaborative Industry Innovator, and Collaborative Business Innovator—are not only ready to use and easier to maintain with no server installation or setup, they also offer the opportunity to collaborate with external manufacturing partners. In addition to the collaboration, communication, and

data management solutions from the **3DEXPERIENCE** Works portfolio, NanoEcho also acquired SOLIDWORKS CAM software to facilitate production.

ACCELERATING TIME TO MARKET, MEETING REGULATORY REQUIREMENTS

By connecting its SOLIDWORKS product development data to the cloud with solutions from the **3DEXPERIENCE** Works portfolio, NanoEcho is further accelerating development, and ultimately time to market, while meeting document control regulatory requirements for medical devices more efficiently and cost-effectively. "The combination of SOLIDWORKS and the cloud-based **3DEXPERIENCE** platform gives us a high-performing and stable platform for developing our product," Skagmo notes.

"The **3DEXPERIENCE** platform's integration with SOLIDWORKS helps with controlling revisions of parts and assemblies," Skagmo adds. "This is a key capability to help us meet the regulatory demands of developing medical devices."

SAVING TIME, AVOIDING SERVER AND SETUP COSTS

Because the data management solution from the **3DEXPERIENCE**® Works portfolio is automated and transparent, NanoEcho is saving a good deal of time and money because it doesn't have to employ a PDM administrator to manage data, purchase a server, or maintain data and hardware as with a traditional PDM system. "Data management on the cloud-based **3DEXPERIENCE** platform is easy to set up and maintain while still providing high performance," Skagmo stresses.

"Initially, we perceived the easing of IT/hardware administrative costs—with no server setup or maintenance—as the most appealing part of the solutions," Skagmo continues. "But since adding **3DEXPERIENCE** Works solutions to our SOLIDWORKS installation, we see the value of inviting all members of the team, including external manufacturing partners, to work with us on the platform."

INCREASING EFFICIENCY IN MANUFACTURING

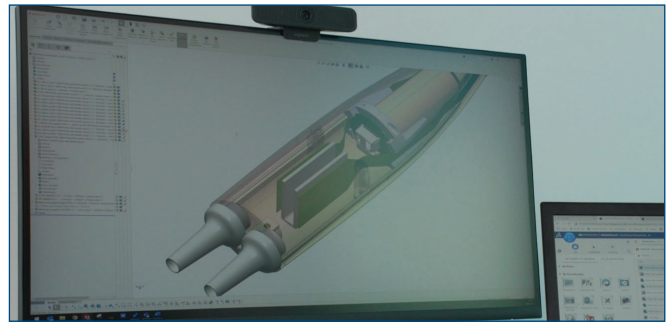
Using SOLIDWORKS and **3DEXPERIENCE** Works solutions in concert, NanoEcho has streamlined communications with its manufacturing partner and increased manufacturing efficiency as a result. "For us, the best part of the **3DEXPERIENCE** platform is the cloud-based collaboration," Skagmo says.

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"It gives us the ability to invite our manufacturing partner to work with us on the platform as a member of our team via a web browser," Skagmo points out. "For example, with SOLIDWORKS CAM, I can show the manufacturer how I intend the part to be machined. This way, I can share the latest original parts in real time. Since our manufacturer also uses SOLIDWORKS, we can share the original file and they can add the G-code for machining. So, for the next part revision, the CAM data is already there and just needs to be updated and we are ready to machine. This will save us time and money. It also means that I can work on parts until our manufacturer tells me to unlock the part so that he can lock it. This workflow minimizes the risk for missed communications and saves time."



Using the transparent, automated data management solution from the **3DEXPERIENCE** Works portfolio, NanoEcho avoids the substantial IT/hardware and administrative expenses of server-based PDM systems because the solution leverages the cloud-based **3DEXPERIENCE** platform, which means that NanoEcho doesn't have to employ a PDM administrator to manage data, purchase a server, or maintain data and hardware as with a traditional PDM system.

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