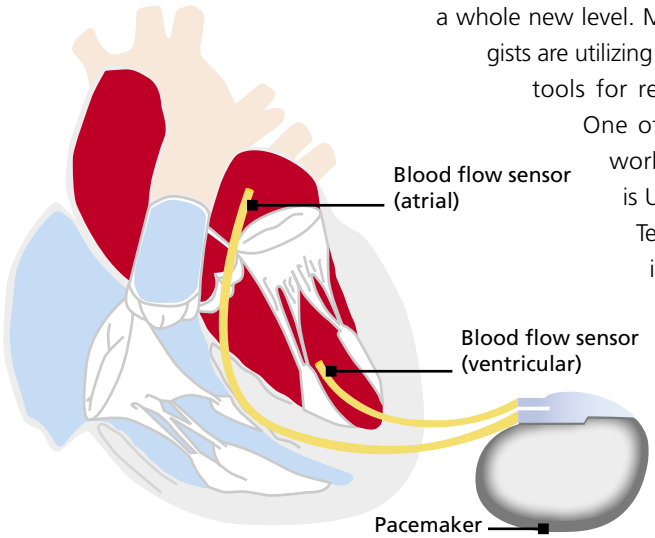
Bypassing The Heart's Control

- dSPACE prototyping system helps medical engineers
- Intelligent blood sensor developed
- Bypass techniques mimic pacemaker

SterlingTech, a leader in providing innovative software solutions for medical device companies, helped a client receive a U.S. patent for an impedance sensor (a device to measure the flow of blood through the heart), after performing a series of experiments utilizing a dSPACE prototyping system, in combination with MATLAB® and Simulink® model-based control design software.

Bypassing Nature's Ultimate Controller

Bypassing is a viable technique in the area of rapid prototyping for optimizing control functions at the real plant, and one that has been traditionally used throughout the automotive and aerospace industries to validate new control algorithms for such mechanical applications as fuel injectors, auto pilot systems and anti-lock brakes. But the medical devices industry is taking rapid prototyping and bypassing to a whole new level. Medical technologists are utilizing rapid prototyping tools for research projects. One of the companies working in this field is US-based SterlingTech, which specializes in software development for medical devices. SterlingTech recently completed a series of real-time prototyping experiments to help a client receive a US patent (patent number: 5,999,854) for an impedance sensor – a device used to measure the flow of blood through the heart.



▲ *The sensors are placed in the left atrium and left ventricle.*

Intelligent Blood Flow Sensor

The sensor is intended to enhance cardiac rhythm management devices, including artificial pacemakers, by improving the measurement and control of blood flow through the heart, as well as preserving remaining battery life and detecting defective lead wires – problems that need to be remedied as quickly as possible for cardiac patients. "The sensors that exist in today's pacemakers are not very good at speeding up the heart when a person is moving or exercising, or slowing it down when a person is at rest," explained SterlingTech founder and president Dan Sterling. "We developed a sensor that can increase or decrease the flow of blood through the heart in real time."

SterlingTech helped its client gain patent approval for its blood flow sensor by generating raw data to fully evaluate and support its validation.

Hearts Under Control

Using a dSPACE protoyping system, along with MATLAB/Simulink model-based design software, C and C++ for Windows/PC, and C and Assembly for the TI DSP (TMS320C4X), SterlingTech was able to build an experimental system to mimic the behavior of an actual pacemaker. The real-time system was successfully used to adjust and control the heart rates of live laboratory animals, both under anesthesia and awake on a treadmill. The system can be looked at as:

- "live laboratory animal" = plant
- "heart" = standard controller
- "dSPACE system" = bypass system to add features to the standard controller

"The system was able to sense the heart's demand for blood and pace the flow of blood through the heart in real time," Sterling said. "The dSPACE equipment was actually running their hearts."

The experimental system was used to run test algorithms, take real-time information from the impedance sensor and, ultimately, control the pacemaker.

The SterlingTech team wrote software to set up and collect data from the sensor, and then implemented a pacemaker that could be configured as the client desired, in real-time, during the experiments. In addition, they created custom Simulink blocks with their new experimental algorithms programmed inside, in a way that could be configured at run time.

Since the experiments were performed on live animals, a high degree of reliability and control had to be maintained, while allowing easy and quick reconfiguration of the computer system.

Replay Program

The automated test capability of the dSPACE system made it possible for SterlingTech to establish a "replay" program. Raw data collected during animal experiments was rerun through the prototyping system with different ideas implemented for the system configuration. This maximized the use of the data collected without having to repeat the experiments. "The systems from dSPACE definitely met our needs," Sterling said. "I would definitely recommend dSPACE products for use in performing clinical studies – especially those involving a lot of variability in parameters and rapid algorithm changes."

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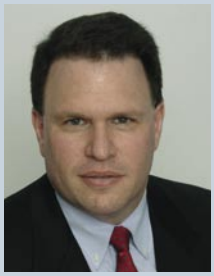
As a result of the data that was produced from the experimental studies, a patent was issued to SterlingTech's client for the impedance sensor. Use of the product on a commercial basis is pending.

Dan Sterling
President, SterlingTech



Dan has been serving as president of SterlingTech since the company was founded in 1988. He has long-term experience with safety-critical software development, including the design and testing of software for implantable and external medical devices, as well as monitoring equipment. His company offers software development and validation services.

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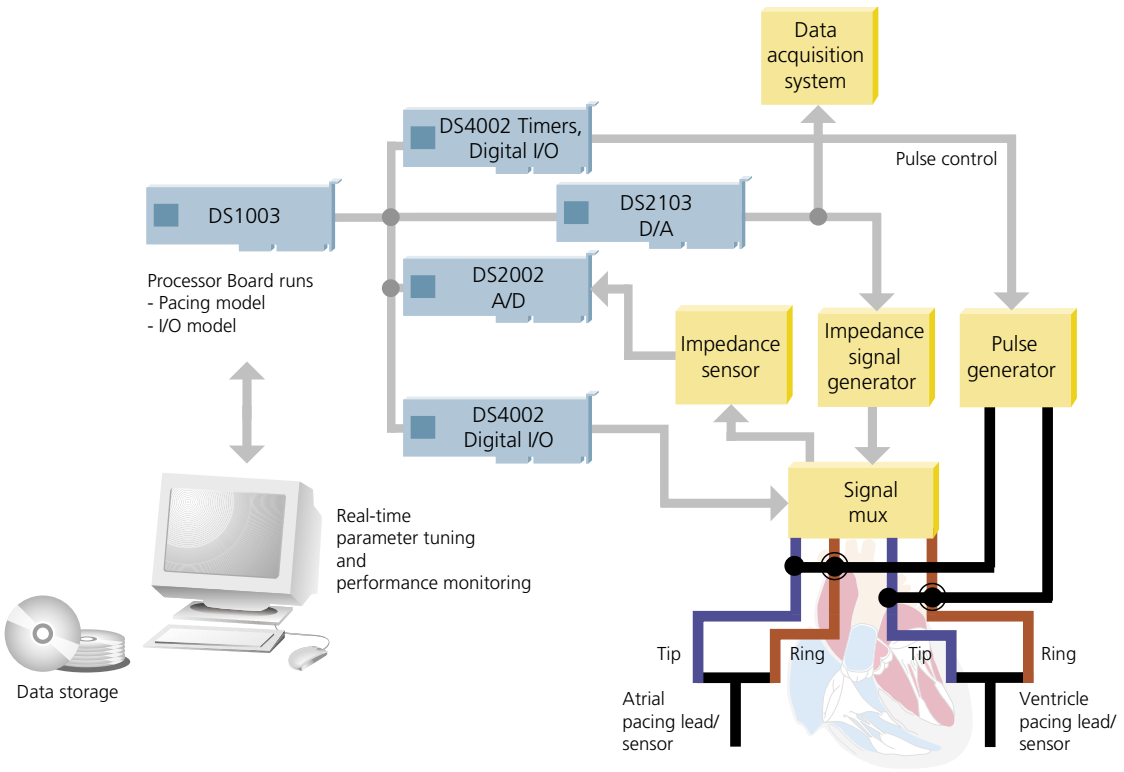

◀ *Schematic of the setup. The lead into each of the heart chambers has two conductors at the end, one is at the tip and the other is a ring around the lead about an inch from the tip. Pacing is performed by creating an electrical current between the tip and ring. Impedance is measured by generating a signal on any of the two leads' tips or rings and sensing on any combination of the others.*