

EXERGEN GLOBAL'S TEMPERATURE SENSOR ENSURES SAFETY, EFFICIENCY FOR ABLATION SYSTEM

Exergen Non-Contact Sensor Plays Key Role in NeuWave Medical's Certus® 140 Cooling System

NeuWave Medical Inc. develops devices that deliver energy to the human body to treat a variety of serious medical conditions. The company's Certus® 140 Microwave Ablation System is the premier soft tissue ablation offering worldwide. It is a platform product with expanding capabilities that can be used in interventional or in surgical specialties, during both minimally invasive percutaneous procedures and in open surgery. The Certus 140™ uses microwave energy at 2.45GHz to maximize power delivery and to create large, predictable ablation zones. The product's small diameter 17-gauge ablation probe more effectively decreases bleeding and other complications when compared with larger diameter probes.

Neuwave designed the Certus 140 to use a CO²-based Cooling System that allows physicians to safely utilize up to 140 Watts of power on a single channel, and ensures the ablation probes' shafts remain cool when delivering microwave energy to the target lesion. The Cooling System including its CO² tanks, the customizable components required for specific ablation procedures, and sockets to plug in as many as three probes at one time are all housed on a compact, portable platform.

A thermal sensor is an essential component of the Cooling System; it measures the CO² tank's temperature in order to gauge its capacity and ensure it maintains sufficient pressure during procedures. If the CO² tank in the Cooling System loses pressure, it will fail to cool the ablation probes and could cause serious injury to the soft tissue. The CO² in the Cooling System also enables Tissu-Loc™, a process that produces an ice ball that can help securing the probe to the tissue during placement, reducing the risk of probe migration.

The Challenge

When Neuwave first developed the Certus 140, it used thermocouple or PT100 contact thermal sensors to measure the CO² tank's temperature. However, the company encountered a series of challenges associated with the use of contact sensors:

- a) It was difficult to install the sensors in a manner that would ensure they maintained contact with the tank. At issue was the fact that tanks can differ in size and shape, and as a result, the contact sensor might make good contact with a large cylinder, but poor or no contact with a smaller one.
- b) Neuwave discovered that if the sensors were mounted perpendicularly to the tanks, they protruded outside of the platform footprint, and could easily be dislodged.
- c) A third challenge was the fact that the contact sensors needed as much as 15 seconds to acclimate before registering an accurate measurement, causing unnecessary delays mid-procedure when



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empty tanks were replaced and sensors were once again placed on them.

The Solution

A team consisting of Exergen professionals, including Dr. Frank Pompei, Founder and CEO, Bob Harris, Industrial Sales/Marketing Manager, and Bram Stelt, Large Account Manager, as well as NeuWave Medical representatives, including Rick Schefelker, VP of Engineering, Jason Blazek, Sourcing and Production Manager at NeuWave Medical, and Yaniv Lazimy, Embedded Systems Engineer, worked side by side to create a custom-sensor solution for the Certus.

The team's first consideration was to identify the type of sensor best suited to the application. The solution required a device that would be easy to mount, yet not easily be dislodged and one that would also fulfill its other tasks. The group then assessed the sensor's field of view. It was important to select a device that could eliminate the area around the tank from its field of view, as inclusion of that view would cause measurement errors. Also, the sensor needed to account for the fact that the tanks used for the application differ in size and material from hospital to the next. Some are painted, some rusty, some shiny aluminum. The different surfaces have different emissivity levels, meaning they will vary in the extent to which they reflect the infrared radiation used by IR temperature sensors. This is especially true for untreated versus treated aluminum, where emissivity differences are huge. These reflective property variances make it difficult to measure surface temperatures.

The next consideration was the speed of the sensor. The sensor used for the system needed to eliminate the delays in registering measurement that were common with the PT100 and thermocouple, and ideally provide real-time measures.



After considering several options, the company selected Exergen's side view non-contact micro IRt/c.SV sensor. With a size of just ¼" in diameter and 1.47" long, the Exergen side view non-contact micro IRt/c.SV sensor integrates easily, securely and unobtrusively into a bracket on the Certus 140's cart. The bracket serves the dual purpose of housing the sensor and preventing radiation from

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surrounding heat sources (for example, a surgeon walking by) to reflect off of the CO² tanks surfaces and create measurement errors.

Since it is a non-contact sensor, the micro IRT/c.SV location on the cart remains constant, eliminating the risk of misaligning cylinders during replacement and ensuring an accurate temperature read at all times. The sensor's < 50 millisecond response time provides real-time measurement and experiences no downtime in temperature detection following cylinder replacement.

Benefits

The custom solution developed by Exergen and NeuWave ensures that the CO² tanks always provide the pressure levels required for the Certus 140 Cooling System to maintain effective and safe temperatures during ablation procedures.

By using Exergen's small-sized, non-contact sensor for its application, NeuWave was able to eliminate misalignments that had occurred when new tanks replaced depleted tanks, and avoid sensor displacement when tanks were switched. Additionally, the Exergen sensor's ability to immediately detect temperatures eliminated the downtime that occurred with contact sensors while they acclimated to the environment.

Neuwave Medical's VP of Engineering Rick Schefelker reports that the response time of the Exergen sensor provides a more accurate and faster representation of the CO² in the tanks, which in turn allows the user to better understand when to change the tanks. Schefelker says that since Neuwave Medical began using Exergen sensors they have seen a huge reduction in the number of service calls the company receives concerning CO² tank status.

"Exergen's unparalleled experience developing unique sensor solutions for both the commercial and consumer medical markets made it the

ideal partner to help use create a temperature sensor for the Certus Cooling System," said Schefelker. "The solution we created is precise, fast and eliminates the confusion, frustration and needlessly replaced cylinders that were common when we employed other possible solutions. The users, surgeons and physicians using the system, are delighted with the solution."

"Through our medical market experience, we knew that the Certus System temperature sensor needed to be both physician-friendly and cost-effective for healthcare organizations," said Dr. Francesco Pompei, Founder and CEO of Exergen Corp. "We combined that experience with our deep knowledge of thermal science and, working closely with the engineering team at NeuWave to create an industry leading solution for the Certus System."

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