



WATERPROOF HOLTER ENABLES TOTAL PATIENT FREEDOM

DMS-SERVICE TURNS TO COMAR MEDICAL TO DESIGN AND ASSEMBLE THEIR NEXT GENERATION CARDIAC MONITOR

The Challenge

Lynda Cole knew that she would need an experienced medical manufacturing partner to support the commercial launch of DMS-Service's next generation Holter monitor, the myPatch®-sl. A Holter monitor is a small, portable device that attaches to the chest for up to two weeks to record and diagnose cardiac rhythm abnormalities.

Ms. Cole, owner of DMS-Service, LLC, first started in the heart monitor industry in 1973 with her father's business, Scole Engineering. She witnessed first-hand the technology evolution that would culminate in the commercial success of DMS-Service's lightweight, wireless, water-resistant myPatch® Holter recorder. Making further refinements to create the waterproof myPatch®-sl required advanced molding and assembly capabilities.

As an ambulatory electrocardiogram (ECG) monitor, Holters are regulated by the U.S. Food and Drug Administration (FDA) as a Class II medical device and supported by a 510(k) regulatory clearance by the FDA's Center for Devices and Radiological Health (CDRH). Therefore, they must be manufactured under the strictest quality controls to ensure federal regulatory compliance and patient safety.

DMS-Service envisioned a game changer with the myPatch®-sl in terms of comfort and convenience. They wanted to introduce a waterproof holter that would allow patients to shower, bath or go for a swim while wearing the device without concern of recorder failure. This would give the patient an unprecedented amount of freedom to enjoy their normal activities without compromising data collection.



CHALLENGE HIGHLIGHTS

- Design multiple electrode shapes in adult, pediatric and neonate sizes.
- Manufacture the Holter monitor so that it is waterproof to a depth of 2 meters for one hour with the ability to record continuously for 14 days.
- Protect the sensitive electronic components during assembly.



"We quickly identified Comar Medical as a supplier that could meet our needs with their full-suite of service offerings." – Lynda Cole owner of DMS-Service.

The Solution

The current generation myPatch® had achieved water resistance via a seal between the two injection molded recorder components designed to protect the internal circuit board and battery from humidity and accidental water intrusion. Comar focused on making the recorder seal hermetic by improving the component design and modifying the ultrasonic welding horn that creates the seal during assembly.

Ultrasonic welding can easily damage electronic components if not done properly. Part of the challenge was to create a joint design to achieve a waterproof seal without harming the electronic circuitry during welding. Simply adding more force, amplitude or time to the welding process had the potential to do more harm than good. Comar's expertise helped achieve this delicate balance.

Similarly, Comar also made design-for-manufacturing improvements by modifying the insert molded electrical contacts on the underside of the recorder and the overmolded activation button on top.

The Results

"It was critical that our supply chain was not adversely affected during the implementation of these improvements," said Lynda Cole. "Our market growth plans could not tolerate any delays. I was very impressed with Comar Medical's ability to execute. All of the design and manufacturing improvements were successful and kept our commercial plans on track. Comar has helped us considerably," added Cole.

"We recognize the benefit that agility plays in being able to bring a quality product to market quickly," states Scott Conklin, Comar's Executive Vice President of Sales & Marketing. "Comar has provided medical device and diagnostic manufacturers this benefit for a number of years. We serve as an extension of our customers' operations and work hard to ensure our customers' success. This agility and broad industry experience enabled Comar Medical to deliver on DMS Service's distinct manufacturing needs."

WHAT THE CLIENT THINKS

"My confidence in Comar's capabilities remains very high. Their continued commitment to excellence has resulted in a true partnership between our companies." - Lynda Cole owner of DMS-Service.

ABOUT COMAR

Comar has been serving the medical, diagnostic, pharmaceutical, and consumer healthcare industries since 1949. We have a reputation for industry-leading design-for-manufacturing, prototyping, diverse molding technologies, and assembly.

Comar Medical's coast-to-coast production facilities are registered to ISO 13485 quality standards and home to ISO Class 7 and 8 cleanrooms. The breadth of our capabilities allow us to focus on and be responsive to the needs of Medical OEMs and their more challenging applications.

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