PRECISION CONCEPTS

Waterproof Holter Enables Total Patient Freedom

DMS-Service turns to Precision Concepts 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.

myPatch®-sl

CHALLENGE HIGHLIGHTS

- **Making further refinements to create the waterproof myPatch®-sl required advanced molding and assembly capabilities.**
- **Must be manufactured under the strictest quality controls to ensure federal regulatory compliance and patient safety.**
- **It was critical that our supply chain was not adversely affected during the implementation of these improvements reagent pack design.**

"My confidence in Precision Concepts' capabilities remains very high. Their continued commitment to excellence has resulted in a true partnership between our companies," stated Linda Cole."

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. Pricision Concepts focused on making the recorder seal hermetic by improving the component design and modifying the ultrasonic welding horn that creates the seal during assembly.

Waterproof Design

DMS-Service envisioned a game changer with the myPatch®-sl in terms of comfort and convenience. The myPatch®-sl would have multiple electrode shapes and be available in adult, pediatric and neonate sizes. DMS-Service wanted it to be waterproof to a depth of 2 meters for one hour and have the ability to record continuously for 14 days. Being waterproof would allow the patient 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.

Choosing a Supplier

“The design objectives of the myPatch®-sl recorder coupled with the quality and regulatory requirements of an FDA-compliant medical device limited DMS-Service’s choices for a manufacturing partner,” cited Lynda Cole. “We quickly identified Precision Concepts as a supplier that could meet our needs with their full-suite of service offerings.”

The Results

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. Precision Concepts focused on making the recorder seal hermetic by improving the component design and modifying the ultrasonic welding horn that creates the seal during assembly.

WHAT THE CLIENT THINKS

“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 Precision Concepts’ ability to execute. All of the design and manufacturing improvements were successful and kept our commercial plans on track. They has helped us considerably,” added Cole.

ADDING FEATURES IMPROVING QUALITY

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. Precision Concepts’ expertise helped achieve this delicate balance.

Similarly, Precision Concepts 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.

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