

## CPRC - Value Analysis

*Why Choosing REM Disposable ECG leads is the Best Option*

### Infection Control

Disposable ECG leads are instrumental in infection control by minimizing cross-contamination risks between patients. These leads, classified as class 2 medical devices subject to stringent cleaning protocols mandated by regulatory bodies like the Joint Commission, alleviate the burdens associated with meticulous cleaning requirements. By eliminating the need for extensive cleaning and disinfection between uses, disposable ECG leads streamline workflow, enhance patient safety, and ensure compliance, all while maintaining efficient and effective patient care in healthcare settings.



### On Government Contract

Rising Eagle Medical ECG leads are on the following government contracts eliminating the need for open market purchasing (Credit Card) and ensuring that Supply Chain Management and the healthcare facility meets VA Directives (1761) and DHA-PI-6430.08

- MSPV Contract: 36C24123A0117 (FORMULARY)
- DAPA Contract: SPO200-23-H-0030 (DMLSS)
- ECAT Contract: SPE2D1-22-D-A008 (DMLSS)



### Fully sourced and Manufactured in the USA

Rising Eagle Medical takes pride in offering disposable ECG leads that are fully sourced and assembled in the USA by a Service-Disabled Veteran-Owned Small Business (SDVOSB). This commitment to domestic manufacturing ensures the highest quality standards while supporting local economies and veterans' employment opportunities. By controlling the entire production process domestically, Rising Eagle Medical can guarantee the integrity and reliability of its products while contributing to the resilience of the American healthcare supply chain.



### SDVOSB

Procuring goods from Rising Eagle Medical a Service-Disabled Veteran-Owned Small Business (SDVOSB) and socially and economically disadvantaged manufacturers (SEDM) is highly advantageous on multiple fronts. By supporting these businesses, organizations contribute to the empowerment of veteran-owned enterprises and economically disadvantaged communities, fostering job creation and economic growth. Furthermore, aligning with government procurement goals, such purchases help meet diversity and inclusion targets. Beyond social impact, SDVOSB and SEDM manufacturers offer innovative solutions, competitive pricing, and tailored services, ensuring quality while driving forward-thinking approaches to market demands. Overall, engaging with SDVOSB and SEDM manufacturers promotes diversity and inclusion and also fuels economic development, spurs innovation, and guarantees the delivery of high-quality products and services.



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### Standardization

Rising Eagle Medical's Disposable ECG leads play a pivotal role in promoting standardization within hospitals by facilitating the use of a single lead set throughout a patient's stay. This continuity streamlines patient care and monitoring, as the leads are compatible with all patient monitors, ensuring seamless integration across various departments and clinics. Moreover, the disposable nature of these leads addresses the common issue of lost or misplaced leads associated with reusable ones, preventing disruptions in patient monitoring. Additionally, by eliminating the need to rewire patients as they transition between clinics or departments, Rising Eagle Medical's Disposable ECG leads enhance efficiency, reduce potential errors, and ultimately contribute to a more standardized and cohesive approach to patient care within healthcare facilities.



### Sustainability

Rising Eagle Medical exemplifies sustainability in manufacturing by prioritizing environmental stewardship throughout its operations and supply chain. Beyond producing high-quality ECG leads, the company demonstrates its commitment to sustainability by recycling any unused materials or residuals generated during the manufacturing process. Moreover, Rising Eagle actively encourages its suppliers to embrace sustainable practices, advocating for the use of recycled materials and energy-saving sources. By sourcing all materials and conducting operations within the USA, Rising Eagle reduces greenhouse gas emissions and ensures compliance with stringent environmental regulations. This commitment not only minimizes environmental impact but also underscores Rising Eagle's dedication to fostering a healthier planet for future generations.



### Quality

Rising Eagle Medical adheres to various standards established by regulatory authorities such as the FDA, as well as standardization committees like IEC and ISO. Please refer to the accompanying chart for a detailed list of these standards which encompass the standards our product is held to as a Class II device.



### Customer Service

Rising Eagle Medical stands out for its unparalleled customer service, driven by the expertise and dedication of its owners, Chris Kelley and Kathy Fortin. With Chris's background as a retired CW4 Medical Maintenance Warrant Officer and Kathy's extensive 20-year experience in medical supplies and consumables, the team brings a wealth of knowledge and understanding to every interaction. Their combined expertise ensures that customers receive personalized attention and expert guidance, whether they have questions about product specifications, need assistance with orders, or require tailored solutions to their healthcare supply needs. Rising Eagle Medical takes pride in going above and beyond to exceed customer expectations, making them the preferred choice for outstanding customer service in the medical industry.



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## Validation and Testing

*The significance of validation and the benefits it offers*

Customer Expectation	Standard	Validation
Clear and Accurate ECG Tracings	<ul style="list-style-type: none"> <li>EC53:2013 5.3.2—Cable and Leadwire Noise</li> </ul>	Validate accuracy by testing the cable to ensure there is less than a 50 uV of triboelectric noise between signal wires when the sample is mechanically manipulated
Wide range of approved cleaning and disinfection methods should disposable leads become soiled	<ul style="list-style-type: none"> <li>ISO 60601-1:2012</li> <li>EC53:2013 11.6.6, 8.8.3 &amp; 5.3.9</li> </ul>	Validate ECG leadwires perform properly after several cleaning cycles with approved agents
Operates within intended hospital conditions with respect to electrical safety	<p>General requirements for safety - Electrical Safety Testing IEC 60601-1:2005 MOD (Part 8.5.2.3) and ANSI/AAMI EC 53:2013</p> <ul style="list-style-type: none"> <li>5.3.7—Contact Resistance (k ohms)</li> <li>5.3.9—Dielectric Electric Withstand and Voltage—Signal to Shield (mA)</li> <li>5.3.8—Leadwire Resistance (k ohms)</li> </ul>	Validate that all voltage and leadwire resistant tests are equal to or perform better than the original ECG leadwire specified
Protects patient skin from allergic, irritation or toxic reaction	<p>Biocompatibility requirement of medical devices—Evaluation and testing that device is non-cytotoxic, non-sensitizing, and non-irritating.</p> <ul style="list-style-type: none"> <li>ISO 10993-5:2009</li> <li>ISO 10993-10:2010)</li> </ul>	Validate all patient-contact materials do not cause harm or irritation to patient skin.
Durable leadwire that can withstand the most demand hospital conditions and mechanical stresses during product life	<p>Mechanical Safety—ANSI/AAMI EC 53:2013</p> <ul style="list-style-type: none"> <li>5.3.3—Flex Life of Patient Leadwire</li> <li>5.3.4—Tesele Strength of Cable Connections</li> <li>5.3.5—Number of Connector Mating/Unmating Cycles</li> <li>5.3.6—Connector Retention Force (N)</li> </ul>	Validate mechanical performance, cycling, flexibility, and connectors for durability.
Tailored to accommodate various patient monitoring vendors, spanning diverse applications and catering to different patient populations and sizes.	<ul style="list-style-type: none"> <li>IEC 60601-1:2005 &amp; ANSI/AAMI EC 53:2013</li> </ul>	Validated for various patient monitoring vendors with different lengths and designed with peelable wire for adjustable fit to accommodate diverse patient sizes.



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