RISING EAGLE
MEDICAL

VALIDATION AND TESTING

THE IMPORTANCE OF VALIDATION AND THE ADVANTAGES IT PROVIDES

RISING EAGLE MEDICAL ECG LEADS

Disposable ECG leads are instrumental in infection control by minimizing cross-contamination risks between patients. Leads are classified as a 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.

WHAT IS THE MEANING OF "VALIDATION"?

Validation involves the essential processes to verify that a product functions according to its specified requirements, ensuring its safety and adherence to predetermined performance standards.

WHAT STANDARDS DO RISING EAGLE MEDICAL ECG LEADS CONFORM TO?

Rising Eagle Medical adheres to various standards established by regulatoryauthorities such as the FDA, as well as standardization committees like Chnage ICE to AAMI 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.

WHAT DOES THE PROCESS OF VALIDATION ENTAIL?

Some tests are performed in highly sophisticated laboratories with specific environmental conditions, for temperature and humidity to ensure that the products will perform properly under these conditions and ensure all material is safe for patients.

Tests in a clinical setting ensure customer needs are met. As part of validation, the Dielectric Withstand Voltage (also known as dielectric strength) test assesses insulation integrity. This crucial test confirms the insulation's ability to withstand high voltages, ensuring safety and reliability in electrical equipment. In addition, multiple tests are conducted for disposable ECG leads, including assessments of flex life, tensile strength, and leadwire resistance.

WHAT MAKES THE VALIDATION OF ECG LEADS COMPATIBILITY ESSENTIAL?

Rising Eagle Medical conducts thorough validation activities for ECG leads, enabling us to confidently stand behind any claims we make about these products. Merely plugging an ECG leadwire into a device and seeing it function doesn't guarantee accuracy or safety. It's crucial to verify that different combinations adhere to standards, ensuring clinicians receive clinically viable data.

DOES USING 3RD PARTY ECG LEADS VOID THE MANUFACTURER WARRANTY

No, the Magnuson-Moss Warranty Act specifies that manufacturers cannot nullify warranties due to the use of non-OEM components. Numerous hospitals opt for non-OEM products, such as blood pressure cuffs (Welch Allyn or Critikon NIBP cuffs) and SPO2 sensors, while disposable ECG leads are a prevalent choice from non OEM suppliers either for cost efficiency or superior quality.

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THE SIGNIFICANCE OF VALIDATION AND THE BENEFITS IT OFFERS

KEY FEATURES INCLUDE: CUSTOMER EXPECTATION	STANDARD	VALIDATION
Clear and Accurate ECG Tracings	EC53:2013 5.3.2—Cable and Leadwire Noise	Validate accuracy by testing then 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	ISO 60601-1:2012 EC53:2013 11.6.6, 8.8.3 & 5.3.9	Validate ECG leadwires perform properly after several cleaning cycles with approved agents
Operates within intended hospital conditions with respect to electrical safety	General requirements for safety - Electrical Safety Testing IEC 60601-1:2005 MOD (Part 8.5.2.3) and ANSI/AAMI EC 53:2013 5.3.7—Contact Resistance (k ohms) 5.3.9—Dielectric Electric Withstand and Voltage—Signal to Shield (mA) 5.3.8—Leadwire Resistance (k ohms)	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	Biocompatiblity requirement of medical devices—Evaluation and testing that device is non-cytotoxic, non-sensitizing, and non-irritating. • ISO 10993-5:2009 • ISO 10993-10:2010)	Validate all patient-contact materials do not cause harm or irritation to patient skin
Durable leadwire that can withstand the most demanding hospital conditions and mechanical stresses during product life	Mechanical Safety—ANSI/AAMI EC 53:2013 5.3.3—Flex Life of Patient Leadwire 5.3.4—Tesile Strength of Cable Connections 5.3.5—Number of Connector Mating/Unmating Cycles 5.3.6—Connector Retention Force (N)	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	IEC 60601-1:2005 & ANSI/AAMI EC 53:2013	Validated for various patient monitoring vendors with different lengths and designed with peelable wire for adjustable fit to accom-modate diverse patient sizes

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