



# Signalife

Clear Data. Trusted Results.

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## PRESS RELEASE

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### **Recom's Heart Monitor Clears Final Regulatory Safety Test — Model 100 Product Now Ready for Market**

STUDIO CITY, Calif.—(BUSINESS WIRE)—Nov. 23, 2004—Recom Managed Systems, Inc. (OTCBB:RECM – News), a leader in innovative design and development of ambulatory diagnostic devices which utilize the company's proprietary signal processing technology, announced today that its Model 100 has now successfully completed all applicable regulatory safety testing requirements of the Food and Drug Administrations (FDA) recognized voluntary consensus standards for general requirements for the safety of medical electrical equipment and IEC 60601-1, and now can proceed to market.

The Company's Director for Regulatory Affairs, Bill Mathew said: "During the past two months, the Company has made significant progress on the regulatory front. This includes successfully passing the stringent Federal Communications Commission (FCC) requirements for Human Exposure to Radiofrequency (RF), the medical device industry's voluntary consensus standards for electromagnetic compatibility (EMC), the consensus standards for ambulatory heart monitoring devices (EC-38), and now, the last safety standard relating to medical electrical equipment (IE 60601-1). Moreover, our test results indicate that our device functions better than previously anticipated. As a result, the Company is looking into the possibility of filing for additional pre-market notifications with the FDA to broaden its claims of performance marketability of the device."

#### About The Model 100 Testing

The FDA recognized medical device voluntary consensus standard for General Requirements for Safety of Medical Electrical Equipment is IEC 60601-1. The FDA voluntary consensus standard program recognizes safety standards that manufacturers can apply during product development to demonstrate safety and performance of their product. IEC 60601-1 is a horizontal international safety standard, encompassing additional standards to address particular aspects of safety for medical electrical equipment, e.g. ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and testing; IEC 60601-1-4 Programmable Electrical Medical Systems. The Model 100 also meets the national deviations for the U.S. (UL 60601-1), Canada (CAN/CSA 22.2 No. 601.1-M90), and the European Union (EN 60601-1). Demonstration of compliance with these standards satisfies both domestic and international markets, e.g. Canada, the EU. The Model 100 was tested for compliance with these standards by Nemko USA in San Diego, California.

## About Recom Managed Systems, Inc.

Recom Managed Systems, Inc. is an emerging life sciences company focused on the monitoring and detection of disease through continuous biomedical signal monitoring. Recom Managed Systems, Inc. uses its patented signal technology to design and develop medical devices that simplify and reduce the costs of diagnostic testing and patient monitoring in an ambulatory setting. With our patented signal technology platform, Recom brings clinical quality physiological signal monitoring to the ambulatory setting.

### Caution Regarding Forward-Looking Statements

Statements in this release that are not strictly historical are “forward-looking” statements. Forward-looking statements involve known and unknown risks, which may cause Recom’s actual results in the future to differ materially from expected results. Factors which could cause or contribute to such differences include, but are not limited to, failure to complete the development and introduction of new products or services, failure to obtain federal or state regulatory approvals governing medical devices, monitoring and other related services or products, inability to obtain physician, patient or insurance acceptance of Recom’s products or services, adverse equity market conditions and declines in the value of Recom’s common stock, and the unavailability of financing to complete management’s plans and objectives. These risks are qualified in their entirety by cautionary language and risk factors set forth and to be further described in Recom’s filings with the Securities and Exchange Commission.

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