



# Signalife

Clear Data. Trusted Results.

Signalife, Inc.  
531 South Main St. ~ Suite 301  
Greenville, SC 29601  
T 864.233.2300  
F 864.233.2100  
www.signalife.com  
info@signalife.com

## PRESS RELEASE

Tuesday December 16, 2004 | 11:28 am ET

### **Recom Completes Fabrication of Its Model 100 Heart Monitor— Technology to Now Be Transferred to Manufacturing**

STUDIO CITY, Calif.—(BUSINESS WIRE)—Dec. 16, 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 has now completed pre-production fabrication of the Model 100 Ambulatory ECG System. The design has successfully passed all applicable regulatory safety testing requirements of the Food and Drug Administration (FDA) recognized voluntary consensus standards for general requirements for the safety of medical electrical equipment and IEC 60601-1, and now can now proceed to market.

Bill Mathews, the Company's Vice President for product development said: "The completion of pre-production prototype is a significant milestone. In conjunction with Battelle Memorial Institute, we have not only completed a fully functional and compliant Model 100 device, but have done so ahead of schedule, within budget and in alignment with FDA's Quality System Regulations. Today's announcement follows the Company recent press releases that it had achieved compliance with all regulatory requirements and industry consensus standards now allowing for a technology transfer to manufacturing. This included the successful passing of 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 the safety standard relating to medical electrical equipment (IE 60601-1). Moreover, our test results validate our device can be used in a transport setting."

#### About The Model 100 Product Development Program

On May 17, 2004, Recom Managed Systems, Inc. and Battelle Memorial Institute, Healthcare Products entered into and have now completed a product development program wherein the Model 100 Battery-Operated, Ambulatory, Digital, Wireless ECG Monitor System was designed to meet all applicable industry consensus and safety standards as required by the FDA approval prior to commercial marketing.

#### 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.

### Contact:

Recom Managed Systems, Inc.

Rodney Hildebrandt, 864-233-2300

Fax: 864-233-2100

Source: Recom Managed Systems