

News Release

FOR IMMEDIATE RELEASE

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Criticare Systems, Inc. announces receipt of FDA 510k approval to market a new, advanced design, portable monitor.

MILWAUKEE--(BUSINESS WIRE)—August 16, 2005--CRITICARE SYSTEMS, INC. (AMEX:[CMD – News](#)). Criticare Systems, Inc. today announced that on August 16, 2005 the company received FDA approval to market its new portable cardiac monitor. This advanced system is intended to monitor physiological parameters of patients within any healthcare environment. The unique design allows a wide variety of optional configurations so it can be tailored for specific market requirements. Criticare developed this product line to be marketed on a worldwide basis where it is important to offer system differentiation to meet the needs of a particular clinical environment.

Among the unique features of the new system is the incorporation of certain popular oxygen saturation and temperature measurement technologies as options to satisfy specific clinical and economic requirements. The company believes this system represents a significant advancement in the capturing of important physiological data in a rapid, flexible manner.

The system will be market launched during Criticare's current fiscal quarter.

Criticare (www.csiusa.com) designs, manufactures, and markets cost-effective patient monitoring systems and noninvasive sensors for a wide range of hospitals and alternate health care environments throughout the world.

This press release contains forward-looking statements. Such statements refer to the Company's beliefs and expectations. Forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those described. Such uncertainties include, but are not limited to, the timely completion of new products, regulatory approvals for new products, the risk of new and better technologies, risks relating to international markets, as well as general conditions and competition in the company's markets. Other risks are set forth in Criticare's reports and documents filed from time to time with the Securities and Exchange Commission.