

Opto Circuits' US subsidiary - Criticare Systems, Inc.'s new modular patient monitor eVision™ 9100 receives US FDA 510(K) Clearance

**Waukesha, Wisconsin, USA | Bengaluru, Karnataka, India
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Criticare Systems, Inc., the wholly-owned subsidiary of Opto Circuits (India) Ltd. (OCI), India's leading developer and manufacturer of patient monitoring systems and interventional products, today received Section 510(K) US FDA (United States Food & Drug Administration) Clearance on new modular patient monitoring system - eVision™ 9100. The latest certification enables Criticare to market and commercially distribute eVision™ 9100 in most parts of the world, particularly in the US, which is one of the largest markets for patient monitors.

eVision™ 9100 is the first modular 'green' monitor that is environmentally friendly and includes a trickle charge solar panel. This expandable, plug-and-play monitor measures physiological parameters of patients; parameters can be removed or changed without interruptions to the operating system. The monitor also has an optional expansion rack providing up to 15 modular slots for an unlimited array of patient monitoring solutions. It is also the only modular monitoring system to include Criticare's patented Water Trap system.

eVision™ 9100 has a touch-screen display and an interactive user interface that allows the base configurations to be easily upgraded in the field (through remote access) or in the factory. Physiological data, system alarms and patient data analysis are made available to the care providers from the monitor.

Commenting on the latest development, Mr. Vinod Ramnani, Chairman and Managing Director, OCI said, "The US FDA 510(K) clearance will now enable us to commercialize eVision™ 9100 in the US and will help boost sales in other parts of the world. Multi-parameter monitors have the largest share in the patient monitoring market. An US FDA cleared modular vital signs monitor in our portfolio will help us capitalize on the market potential."

The global revenue for multi-parameter patient monitors is estimated to be around US\$ 2249 million. (Source: Global Markets Direct).

Multi-parameter patient monitoring devices are used to monitor more than one patient parameter. eVision™ 9100 will monitor parameters such as Non-Invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), Temperature, Respiratory Gases, Anaesthetic Agent Gases, Respiratory Rate, Pulse Oximetry, ECG and Arrhythmia and ST Analysis of the ECG waveforms. The monitor will be used in critical care and preoperative units and during surgery and emergency care.