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Maquet Critical Care Receives FDA 510(K) Clearance for its SERVO-I Ventilator with NAVA

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Maquet Critical Care announced that it has received 510 (K) clearance by the U.S. Food and Drug Administration (FDA) to market the company's SERVO-I ventilator with the NAVA (Neutrally Adjusted Ventilatory Assist) option. According to Maquet, NAVA is a new approach to mechanical ventilation which allows the patient's respiratory center to control the ventilator, thereby improving synchrony between patient and ventilator. SERVO-I with NAVA is intended for treatment and monitoring of neonatal, infant and adult patients. The improved synchrony helps minimize patient discomfort and agitation while it promotes spontaneous breathing. Signals from the respiratory control center in the brain are transmitted through the phrenic nerve to the diaphragm, where a catheter captures the electrical activity (EDI) and feeds it to the ventilator. The ventilator responds by providing the requested level of support to the patient. As the ventilator and diaphragm work with the same signal, the coupling between the two is virtually simultaneous.

In addition to being a distinct mode of ventilation, NAVA also enables a complete evaluation of the neural respiratory control by capturing the electrical activity of the diaphragm. The EDI signal can be used as a unique monitoring tool as it provides information on respiratory drive, volume requirements, effects of ventilatory settings and to gain indication for sedation and weaning.

Sales of SERVO-I with NAVA are expected to begin in 2007. Current SERVO-I users have the possibility of upgrading their system with the NAVA option as the only required additional equipment is NAVA software, an EDI module and an EDI catheter.

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