A COMPUTER-ASSISTED PERSONALIZED SEDATION SYSTEM

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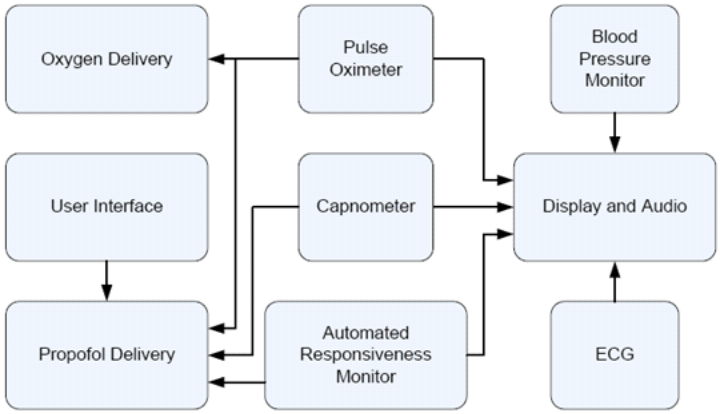
Introduction: The SEDASYS® System is an investigational computer-assisted personalized sedation system that is designed to facilitate the administration of minimal-to-moderate sedation with propofol. The system was designed using the ASA Practice Guidelines for Sedation and the FDA approved propofol labeling. The system provides many safety elements proposed by the anesthesia medical community based on decades of study and experience.

Implementation: The monitors included in the system are a pulse oximeter, a capnometer, electrocardiogram, non-invasive blood pressure, and a novel Automated Responsiveness Monitor (ARM). The ARM assesses the patient's response time to mild verbal and tactile stimulus. The drug delivery algorithms in the system were designed to: 1) achieve the desired clinical effect without overshoot, 2) adhere to dosing recommendations for sedation with propofol, and 3) enable precise titration of minimal-to-moderate sedation. Monitoring is integrated with drug delivery by employing rate limits and reductions based on the ARM. Propofol delivery will stop in response to decreased oxygen saturation or apnea. Oxygen is delivered at a rate that is depended on the patient's arterial saturation.



Schematic of a Computer Assisted Personalized Sedation (CAPS) System

Discussion: The system presented integrates ASA recommended monitoring with drug infusion algorithms that are consistent with the propofol label. The system continuously monitors and responds to the patient's physiological status. The integration of controlled infusion and monitoring provides a safe and effective means to deliver propofol.

References:

1. ASA, Practice guidelines for sedation and analgesia by non-anesthesiologists. Anesthesiology, 2002. 96(4): p. 1004-17