"iCuro"™ (Intensive Care Unit Real-time Observer) :
A Real-Time ICU Patient Data Integration and Presentation System

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Specific Purpose & Problem Statement: In most intensive care units (ICUs), clinical data acquisition and integration relies upon time-consuming human intervention to create huge paper flowsheets, a practice that creates "information overload", errors, fragmented medical decision making and long-term archiving problems.

We have developed, tested and FDA certified a new type of computer system that is officially a 510K device. The iCuro™ System is a bedside, networked, movable machine that automatically acquires and integrates time-stamped monitor, ventilator and infusion pump data, with patient data from labs, specialty devices, and bedside observations. iCuro™ has a secure, HIPAA-standards compliant architecture, and is locally configurable using push-button set-up and an integrated HL7 mapping utility. The iCuro™ device provides real-time access to trended clinical information streams at the bedside, or offsite, at the iCuro Control Center™. The iCuro™ user interface gives each treating clinician flexibility to generate "their" integrated information set on demand, in the desired format. The device also automates nurse and respiratory therapist charting, and concatenates user-entered and machine-acquired data onto "zoom-able" trend graphic panels and paper reports. iCuro™ fully supports neonatal, pediatric and adult critical care processes.

Innovation: The iCuro™ System integrates bedside device communication, using a robust, real-time, temporal database, and secure systems architecture to gather and store clinical data from dissimilar medical monitoring devices and archival Hospital Information Systems (HIS). The iCuro™ System has a library of device interfaces to automate data gathering to a temporal database that semantically processes the diverse data elements, stores data by assigned time stamp and returns fast, real time trends for all multi-source data. This totally integrated bedside device supports ~2500 clinical data elements needed across all types of critical care units. The system is configurable at every level from individual user to enterprise access and audit rules. To our knowledge, this is the first fully-integrated, HIPAA-compliant device of its type to reach market.

System Description: The FDA and UL-approved bedside system uses high-speed hardware attachable to the bedside, wall or mobile cart. User interfaces are touchscreens, optional keyboards and/or mouse. The interface presentation engine displays assembled data in many formats, including graphical reports. Temporal matching and correct chronologic back-posting of asynchronously arriving data (e.g. lab results) with machine-generated clinical information (e.g. vital signs) is precise (R=99.9% correct, p< 0.001). The architecture will integrate with a hospital’s HIS, enhancing documentation for quality assurance and billing. To our knowledge, this real-time approach to temporal synchronization and open-standards management of automatically acquired multi-source clinical data elements is a unique contribution.

Deployment Statement: We hypothesize that iCuro™ will improve outcomes by presenting a faster, more comprehensive view of patient condition to bedside caregivers, by reducing "missing data" errors and by allowing critical-care clinicians to focus on the patient instead of on the daily search for data. The system has been beta tested in the use environment in multiple hospitals. ICU DataSystems, Inc. has contracted with a device marketing firm and is in negotiations for networked installation in an academic Pediatric Intensive Care Unit, and in a private, Level 2 Neonatal Intensive Care Unit.

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