The Integrated Clinical Environment (ICE) Data Logger-Opportunities and Advantages Relative to Individual Device Data Logging

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**Introduction:** Medical devices have had some level of data logging capabilities for decades. The data logs are not standardized as to content or format and may include device performance metrics for technical troubleshooting and maintenance, and clinical data for patient care. These logs are downloaded as needed to perform an adverse event analysis, but even if one device log is fairly “complete”, a log of the entire clinical picture including data from all devices in use at that time, is not available. For example, in typical complex clinical environments (e.g. OR, ICU, ED) the time-aligned integration of data streams from multiple devices – each with its own proprietary communication protocols and algorithms, time base, and physical interfaces – offers numerous challenges. An integrated data logging capability is needed for the entire clinical environment in which the patient is being monitored or is receiving therapy – to include logging of commands, device connection and disconnection, physiologic and technical alarms, patient physiologic data, and other device status information. [1]

**The Problem:** The data logging capabilities and characteristics of selected medical devices with varying capabilities – including ambulatory data loggers (e.g. digital Holter recorders), handheld monitors (e.g. combined SpO2 and CO2), laboratory data recorders (e.g. sleep diagnostics systems), multi-parameter respiratory monitors, multi-parameter physiologic monitoring systems, anesthesia workstations, and ventilators – vary significantly with respect to the capabilities, data formats, and bandwidth requirements. Given the wide range and differences in device output data streams and capabilities, it is daunting to try to combine measurements from devices from different manufacturers and sometimes even the same manufacturers. This is further complicated by the need for efficient mechanisms for data playback for adverse event/near-miss investigation and reporting. The ability to playback data sets does exist, but is limited in scope. For example, ambulatory ECG recording devices have developed a sophisticated suite of tools for the playback and analysis that data.

**Proposed Solution:** A data/patient-centric approach as defined in the ICE standard [2] will allow plug-and-play devices using data-centric protocols and an ICE data logger to work seamlessly, in an open, standardized, and time-synchronized manner, as compared to individual device-based approaches. The advantages include more efficient adverse event/near miss analysis, common terminology and time base, and improved security. Such an approach permits new opportunities for improved patient monitoring and safety. This is distinct from the capabilities of the EHR, which uses lower granularity data storage (e.g. one minute) and can fail to capture clinically significant outliers. [3]
With each device uniquely identified (e.g. FDA UDI) and data formatted in a standardized form, new opportunities for improvements in adverse event investigation will be enabled, similar to those enabled by the data recorders used in transportation and flight data recorders. Challenges with current approaches to adverse event analysis, including device location and sequestering, manual data entry, differences in clock timing, and problems with data extraction, are reduced. Debugging logs including network interactions can facilitate sophisticated debugging of device and operator interactions, which may assist with clinical event analysis. Significant work will be required to develop effective playback tools.

References:
2. ASTM F2761-09(2013) Medical Devices and Medical Systems – Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) – Part 1: General requirements and conceptual model.