MEDICAL DEVICE DATA
EMPOWERING CLINICIANS & IMPROVING OUTCOMES

CapsuleTech.com
The Capsule medical device information platform (MDIP) is designed to support a hospital’s need to leverage device data in unlimited ways. With deployments in over 2600 leading healthcare facilities across 40+ countries, Capsule’s solution is proven to work in any care setting. Improving clinical workflow and data reliability for clinicians, Capsule also provides flexibility, scalability and security for biomedical and IT staff.

**Capsule Anticipates & Manages the Complexities of Device Integration**

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**Capsule Provides:**
- The industry’s most extensive library of device drivers for a broad range of device types, manufacturers, and versions
- Connectivity options to fit any care environment
- Plug-and-play connectivity, self-service management model

**Capsule Manages Disparate Data & Prepares It for Use**

The data generated by the array of medical devices in a typical hospital offers a wealth of information including patient data, therapy details, alarms and device settings. Unfortunately, there is little standardization as to how medical device data is output and labeled, so important context — location, associated patient, correct time, and other corollary elements — is often missing.

Destination systems, too, require different types of data from different devices. For example, the EHR requires patient vitals every minute for clinical documentation. Alarm management systems, however, need alarm and contextual information as soon as it is communicated by the device.

**Medical Device Data: A Critical Asset, Today & Tomorrow**

In today’s healthcare environment, data is predicted to be the strategic resource that will drive the real-time health system — creating insights to improve patient outcomes, create operational efficiencies, and support new care models. Currently, however, it is estimated that less than 1 percent of medical device data (MDD) is being used for digital health — mainly for clinical documentation, i.e. sending parameters to an electronic health record (EHR) (Capsule calculation, 2019).

Recently, many health systems have embarked on patient care and administrative innovations — initiatives that can enable predictive bedside interventions, close the gaps on patient safety and reduce workflow inefficiencies. These initiatives require that data — specifically medical device data — be available in greater types, quantities, and frequencies, but current IT infrastructures are ill-equipped to deliver this data to the right systems.

**Percentage of Medical Device Data Currently Being Used for Digital Health**

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CAPSULE ALLOWS HEALTH SYSTEMS TO DELIVER COMPLEX MEDICAL DEVICE DATA TO SYSTEMS THROUGH POWERFUL DATA MANAGEMENT CAPABILITIES:

- **DATA SELECTION**: Send all parameters or filter and send a subset of parameters as required by the receiving system(s).

- **DATA SAMPLING RATE**: Send data at the appropriate pace. Deliver clinical alarms in near real-time as they are produced, while sending patient vitals every minute for clinical documentation.

- **DATA TRANSFORMATION**: Send data in specific formats such as exact parameter labels, units, or codes. For example, 1-2-3 can become low-mid-high.

- **DATA CONTEXTUALIZATION**: Add and send contextual data such as location, patient ID, user ID, time stamp, etc. to make data more meaningful. Most medical devices have no contextual awareness and cannot provide this data directly.

**UNIQUE MEDICAL DEVICE DATA REQUIREMENTS BY CLINICAL INITIATIVE**

<table>
<thead>
<tr>
<th>TYPE / DEPARTMENTAL DOCUMENTATION</th>
<th>PARAMETERS</th>
<th>FREQUENCY OF DATA</th>
<th>CONTEXTUAL DATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitals</td>
<td>Subset</td>
<td>Periodic, Episodic (based on measurement frequency, ex: q2h)</td>
<td>Patient ID or Location, Device ID, Clinical Observations, Time Stamp, User ID</td>
</tr>
</tbody>
</table>

**ALARM MANAGEMENT**

| Vitals | Subset | Streaming | Location, Device ID, Data Correlation, Time Stamp |

**EARLY WARNING SCORING (EWS)**

| Vitals | Subset | Periodic or Streaming | Patient ID or Location, Data Correlation, Time Stamp |

**ALARM SURVEILLANCE**

| Vitals | Alarms Waveforms | Subset | Streaming | Patient ID or Location, Device ID, Data Correlation, Time Stamp |

**PATIENT SURVEILLANCE**

| Vitals | Alarms Waveforms | Subset | Streaming | Patient ID or Location, Device ID, Clinical Observations, Data Correlation, Time Stamp |

**CLINICAL RESEARCH**

| Vitals | Alarms Waveforms | All | Streaming | Patient ID or Location, Clinical Observations, Time Stamp |

**CARE EFFICIENCY & DOCUMENTATION ACCURACY**

In high acuity environments where patients are connected to multiple medical devices, Capsule’s Vitals Stream provides scalable, plug-and-play bedside connectivity. In lower acuity environments, Capsule’s Vitals Plus and Chart Xpress capture patient vitals, bedside observations, and send validated information directly to the EMR. With options to meet both the clinical and technical requirements of various care areas, Capsule reduces transcription errors, improves the bedside workflow and makes information immediately available to the entire care team.

**MORE MEANINGFUL CLINICAL ALERTS THROUGH DATA CORRELATION**

Because Capsule can correlate and send device data for display in alarm management systems, clinicians no longer have to correlate the alarm and patient status manually. This capability facilitates earlier data-driven interventions and reduced alarm fatigue.

**IMPROVED OPERATIONAL PERFORMANCE**

Less clinical disruption, system-wide IT efficiencies, and clear insight into medical device asset management — Capsule IQ utilizes the data flowing through the Capsule MDIP to provide dashboards and configurable notifications to proactively manage your medical device connectivity infrastructure.
DATA-DRIVEN ALARM REDUCTION & EARLY IDENTIFICATION OF AT-RISK PATIENTS

Capsule’s Early Warning Scoring System and Bernoulli’s clinical surveillance applications give providers a safer, more efficient way to monitor patients and identify developing patient conditions. In a clinical study of patients diagnosed or suspected to have Obstructive or Central Sleep Apnea, Bernoulli real-time analytics generated 99% fewer alerts than the bedside devices, yet successfully identified every patient that experienced actual respiratory depression early enough to avoid a major escalation in care, such as the need to intubate or transfer to the ICU (Supe, 236-251).

BERNOULLI’S RESPIRATORY DEPRESSION SAFETY SURVEILLANCE (RDSS)

<table>
<thead>
<tr>
<th>Utilizing Standard Device Alarm Thresholds</th>
<th>Applying Conventional Alarm Delay Techniques</th>
<th>Total Issued Alerts Using Bernoulli’s RDSS Analytics</th>
</tr>
</thead>
<tbody>
<tr>
<td>99% Less Alarms</td>
<td>No Missed Actual Patient Events</td>
<td>No Need to Intubate or Transfer to ICU</td>
</tr>
<tr>
<td>Total issued device alarms (capnographs and pulse oximeters, excluding technical alarms)</td>
<td>Total issued alerts using 30-second sustained alarm criteria</td>
<td>Note: alerted for all actual respiratory depression episodes</td>
</tr>
<tr>
<td>22,812</td>
<td>13,272</td>
<td>209</td>
</tr>
<tr>
<td>42% Reduction</td>
<td>99% Reduction</td>
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