Abstract

Health Information Technology (HIT) initiatives like "meaningful use," Accountable Care Organizations (ACOs) and the Hospital Readmission Reduction Program have created a strong push for medical device data to be integrated with Hospital Information Systems (HIS). At the same time, the Patient Protection and Affordable Care Act (PPACA) is forcing effective remote patient monitoring to enable care providers to more effectively manage diseases and avoid penalties for excess readmissions. The net result is the requirement for device integration with a provider’s electronic medical record (EMR) system to enable remote patient monitoring.

Hospitals and small practices are looking for medical device data to be more interoperable, complete, standardized, detailed, and accurate to improve clinical outcomes and patient safety. Interoperability can be achieved by several different parties: the medical device manufacturer, the middleware vendor, the system integrator, the healthcare delivery organization (HDO), or the physician. Preferably, the medical device manufacturer should design and build products to be interoperable or provide an alternate connectivity solution.
Key Drivers and Challenges

Key Drivers

• New regulations such as “meaningful use” requirements, the implementation of ACOs and other recent changes in federal healthcare law and regulations, such as Medicare and Medicaid financial incentives and penalties are driving change. For example, the Stage 2 meaningful use requirement for documenting blood pressure in an EMR will increase from 50% to 80% for all effected patients. Manual recording of this data will become increasingly difficult, inefficient and error prone.
• The need to more accurately analyze patient and device data, to support improved healthcare quality and outcomes.
• Documentation and workflow automation to improve patient safety, healthcare quality, and provider efficiency and compliance.
• HDO resources needed to maintain customized interfaces and maintain manual data feeds from devices.
• Remote patient monitoring to improve healthcare and cut costs through shorter in patient stays, reduced readmissions and less-frequent office visits.

Challenges

• Lack of standard interfaces – new devices frequently require a customized integration effort, involving valuable development resources.
• People and technology – developing and supporting solutions for integration with a HIS is not a core competency of medical device manufacturers and has the potential of wasting core resources in failed attempts in tackling them. Mobile and cloud enablement requirements make this even more of an issue.
• V&V cost – post sale custom interface development for device integration requires additional verification and validation to ensure solution accuracy and completeness. This increases the total cost of device ownership for HDOs, making their purchase less attractive.
• The transition of point of care (PoC) from hospital to home provides opportunity to have a better consistent and timely interaction between patient and doctor making cloud and mobility driven medical devices a major trend.
• The growth of telehealth or telemedicine technologies are facilitating the device transition as remote monitoring of patients by doctor or hospital becomes a reality.
Infosys Point of View

Infosys analyzed the requirements for a secure and extensible connectivity solution that integrates devices with healthcare information systems in a quick and seamless way. There are six core requirements that must be met to make this happen:

- Interoperability - interfacing with medical devices that use different communication protocols
- Data acquisition, translation and standardization
- Ability to interface with EMRs using standard protocols
- Custom interface support
- Seamless data exchange with HIS’
- Data security and reliability

Infosys Medical Device Connectivity Solution

Infosys medical device connectivity solution acquires, renews and uploads device data into standard formats providing seamless data flow between devices and information systems. Once available, HIS’, EMRs and Clinical Information Systems (CIS’) can access stored device data for diagnosis and treatment providing better patient care.

The solution includes a software development kit (SDK) which allows access to patient demographics and device data using application programming interfaces (APIs) for EMR integration. Components for reporting, alarm management and analytics are provided which can be used as ‘plug-ins’ in the EMR application.

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**Device Manager (PC/Mobile device)**

- **Medical Devices**
  - File Listener
  - RS232 Listener
  - Socket Listener
  - Bluetooth
  - Wireless
  - USB

**Device Manager (Web Platform)**

- **Presentation Layer**
  - Admin UI
  - Configuration UI
  - Audit & history UI
  - Diagnostic reports UI

- **Device SDK Connectivity APIs**
  - Device Data upload
  - Authentication
  - Remote Diagnostics

- **Business Layer**
  - User Provider
  - Admin
  - Audit Trails & Logging
  - Licensing
  - Security
  - Configuration

- **Data Access Layer**
  - Data store

**EMR/HIS (PC & Mobile Platform)**

- Reports
- Analytics
- Alarms

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Features

- **Anywhere anytime connectivity** - wired and wireless connectivity for medical devices via computer or mobile device managers that upload data
- **Support** for clinical as well as personal healthcare devices with HIS
- **Multiple connectivity options** – supports communication over Wi-Fi, Bluetooth, ZigBee, USB, Ethernet, RS232 and Web interfaces for smooth and easy connectivity between medical devices and information systems
- **Standard based approach** – uses the healthcare enterprise (IHE), IEEE 11073 (Continua compliant) standards for medical device integration for smooth and seamless connectivity
- **Support for legacy devices** – provides device manager plugins for legacy devices for data acquisition and transformation into standardized formats
- **Data security and compliance** – provides secure access to patient data through HIPAA compliance
- **EMR integration** – provides a SDK to help smooth EMR integration
- **Multi-modality and multi format support** – supports health level seven (HL7), digital imaging and communication in medicine (DICOM), standard communications protocol for computer assisted electrocardiography (SCP-ECG) and reshape proprietary data into standard formats for multiple modalities
- **Configurable data storage** – allows device data storage with different databases (e.g. SQL, Oracle.)
- **Flexible user interface** – supports customization of user interface per device modality
- **Extendible and reusable** – provides plugin architecture for report generation, alarm management and analytics modules for extensibility
- **Audit trails and logging** – maintains audit trail and logs of all the user actions

Benefits

- **mHealth** – anytime, anywhere service through mobile devices and wireless technology giving it an edge over wired-only solutions
- **Reduced deployment costs** - compatible with configurable data storage option of existing HIS/EMR databases in hospitals or small practices, reducing deployment and database licensing costs
- **Quicker and cost efficient integration** – standards-based approach leads to timelier and cost efficient integration of medical devices with healthcare informatics