EMRGateway

Interoperability solution for medical devices

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Abstract

New technologies are being introduced in hospitals and labs at an ever-increasing rate, and many of these innovations have the potential to interact synergistically if they can be integrated effectively. The need for "plug-and-play" interoperability – the ability to take a medical device out of its box and easily make it work with one's other devices or applications– has attracted great attention from both healthcare providers and industry.

EMRGateway is one such software solution that automates the process of data capture by connecting simultaneously to various health, fitness, laboratory, medical devices enabling seamless and flexible connectivity with any clinical system in the hospital IT infrastructure (EIS, HIS, Therapy specific desktop application etc). The solution supports device connectivity by interfacing with devices that use proprietary as well as standard based protocols (IEEE 11073/x73) while it uses HL7 for integration with clinical application.

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Introduction

Today, majority of the healthcare delivery enterprises and departmental clinical systems are still working in silos and lack interoperability with medical devices. This has emerged as a major hindrance to effective utilization of the data available from these devices for superior care delivery.

Interoperability helps patients get the most out of technology; it also encourages innovation in the industrial sphere. When different devices can be combined without complicated and expensive interfaces, small companies can enter a field and make specialized products. Without interoperability, hospitals are forced to turn to large vendors that provide suites of compatible devices but that do not specialize in any one area. Interoperability promotes competition, and encourages innovation and quality.

Standard based medical device connectivity solutions will automate data capture process; advance the data precision and assist integration of the patient medical facts into clinical workflows without a glitch.

Market Situation

From the perspective of producer of consumer healthcare devices, there are six major factors that affect an industry's ability to achieve interoperability.

- There needs to be a demand for interoperable products.
- There must be standards, or rules, defining what interoperability means in the field.
- Business conditions must encourage manufacturers to make their products interoperable.
- Compliance must be verified by independent testing
- Guidelines must exist that make the often-complicated standards easier for companies to interpret.
- Interoperability must be actively promoted. The rapid rise of wireless technology illustrates that interoperability is attainable.

A potential market of interested hospitals exists, and standards for interoperability are being developed. Nevertheless, it seems that current business conditions do not encourage manufacturers to pursue interoperability. Only sixteen to twenty percent of hospitals, for example, use electronic medical record (EMR). With such a low rate of EMR adoption, most manufacturers can get away with not investing in interoperability. By promoting EMR adoption, healthcare companies hope to create an environment in which hospitals will have the collective leverage to demand interoperable products.

The current market scenario demands to adopt the latest technologies and emerging standards like HL7, IHE and Continua for better medical solutions and improved patient safety. Many OEM's and major players like Google and Microsoft are involved in standardize and automate diverse healthcare processes to offer a trouble-free and competent ways for Patient and physicians to handle medical records and treatment information in a secured, easily manageable & accessible manner.

Problem Definition

The current market situation widely opens a prospect to define an Interoperable solution to connect the various medical devices which can be used in patient home or in an operation room or in ICU's and other hospital systems. As most of the devices run with the proprietary protocol defined by the device manufacturer and with different ways of connecting the devices to a PC (Serial port, USB, Bluetooth etc), it makes the Hospital support staff/caregiver to spend more time on setting up the devices to gather the data and use it in the application which aid them for a healthier decision support.

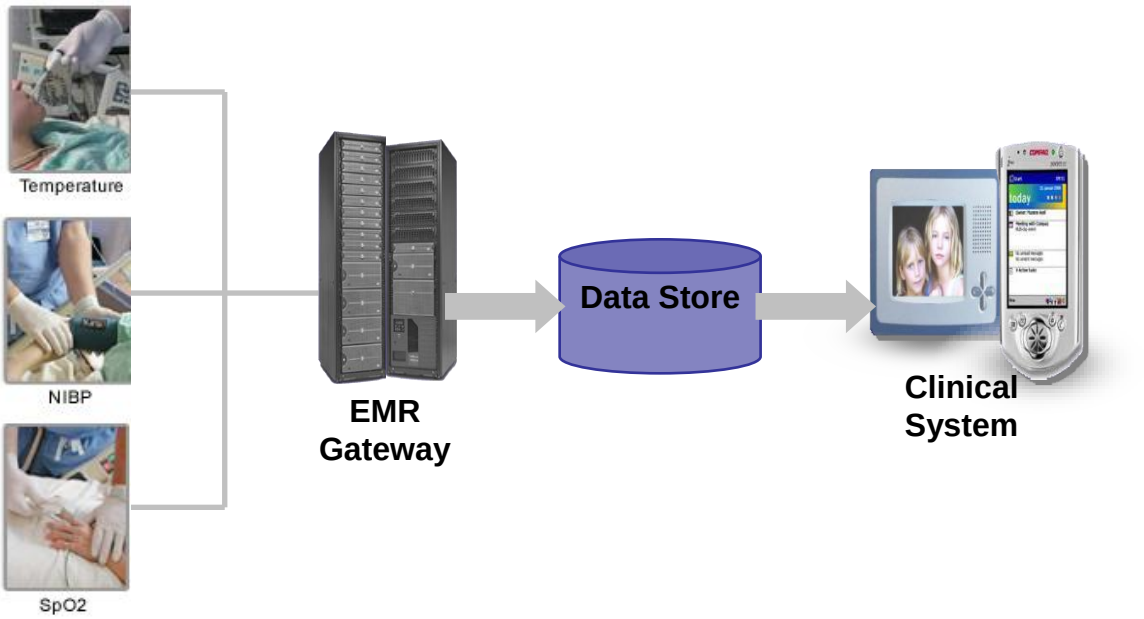
Most of the time, the medical data collected from various devices needs to be stored in a repository for advance scrutiny and also can be used by HIS/MIS and other applications for superior treatment to the patient. The patient data are vital and private as no patient would never like to share their health concerns with anybody else.

There are standard defined by different committees and healthcare organization for medical devices connectivity and data transfer between devices and clinical systems. IEEE defines standard for device connectivity (IEEE 11073), HL7 (Health Level 7) is the standard for electronic interchange of medical information among healthcare systems. Integrated Healthcare Enterprise (IHE), a framework to ease the assimilation of, and information flow between, various medical information systems in a healthcare enterprise. These standards are either not broadly adopted or adopted by OEM's / healthcare organizations in isolation and overall solution exist in silos

The present circumstances of limited-non standardized medical devices connectivity and lack of interoperability leads us to define a solution which would standardize the way to connect diverse medical devices with clinical systems and define a workflow to deal with various decision support systems with improving patient wellbeing and healthcare effectiveness

Solution Approach

EMRGateway is a software solution that automates the practice of connecting simultaneously to various health, fitness, laboratory, medical devices enabling seamless and flexible connectivity with any clinical system in the hospital IT infrastructure (EIS, HIS, Therapy specific desktop application etc). The solution supports device connectivity by interfacing with devices that use proprietary as well as standard based protocols (IEEE 11073/x73) while it uses HL7 for integration with clinical application. At high level, the overall solution follows the framework approach defined by IHE but tailor the solution to support assorted communication protocol defined by different device OEM's and standard protocol like X73.



EMRGateway Usage Modal

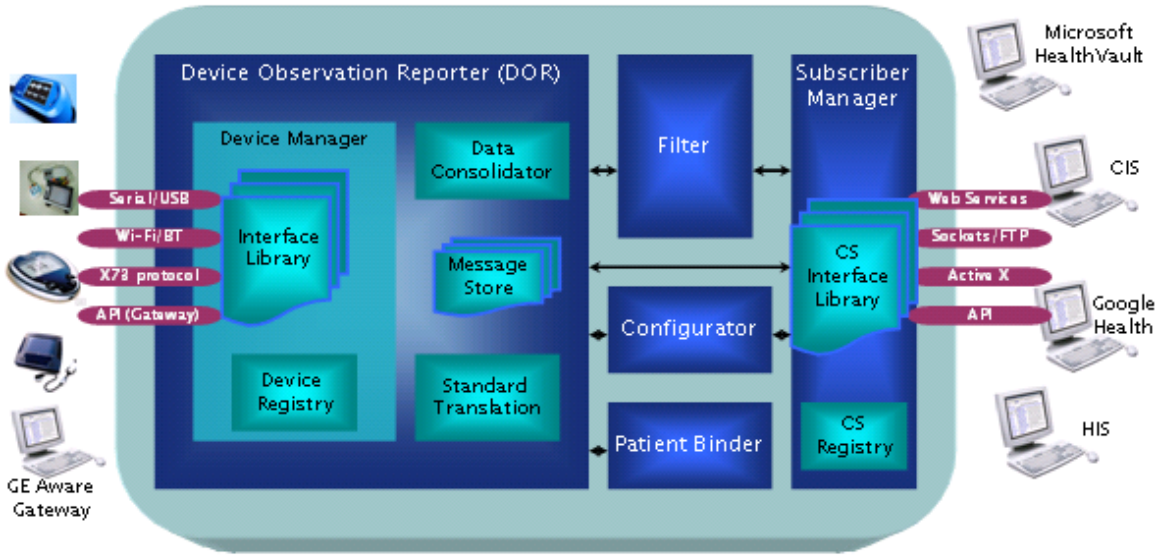
Above diagram illustrate the overall picture and usage modal of anticipated EMRGateway solution.

EMRGateway provides a framework to connect the devices through serial port, USB, Bluetooth and establish communication channel with each device & start collect the data. The collected data are getting converted into HL7 format and to be stored in the data store systems. The data store can be Healthcare enterprise specific databases or public storages like Google Health & Microsoft health vault.

The clinical system will be interacting with data store to collect the data and provide diverse functionalities like trend analysis, Charting, Reports and other vital features which would enable the Clinicians to provide a healthier solution for better health for a patient.

Technical Architecture

The technical approach for EMRGateway solution is based on IHE patient care device technical framework (PCD-TF) & uses Continua X73 standard for device connectivity and HL7 to transfer data from EMRGateway to external EIS/HIS clinical applications



EMRGateway – Architecture Diagram

The overall solution of EMRGateway is based on IHE architecture which consists of Device Observation Reporter (DOR), Device observation Filter (DOF) and Device observation Consumer (DOC)

DOR is responsible for connecting to various devices and collect the data and send to DOF or DOC, based on the defined workflow.

DOF takes the filter configuration from medical devices and accordingly construct the data which it receives from DOR and send to DOC.

DOC collects the data either directly from DOR or through DOF based on the filter setup given by the external clinical systems which makes use of the data coming from DOC

In the above architecture diagram, DOR and DOF components are defined and the subscriber manager acts as a Device Observation Consumer (DOC)

Device manager

Device Manager Component is responsible for maintain the devices which are connected to EMRGateway using serial/USB/Bluetooth etc and collect the data from those devices and pass it to underlying components.

Interface library module maintains the libraries/plug-ins for various devices, gateway systems (GE Aware gateway, Philips IntelliVue Information center etc) and X73 manager components

The devices gets registered and the plug-in and profile of the devices will be maintained in Device registry. Whenever the device gets connected to this system, Device manager gets the notification from the device. The device registry checks the availability of the profile of that device and initiates I/O abstraction layer to initiate the communication based on the mode of connectivity (serial/USB etc).

If the connected device is X73 enabled, the X73 manager gets initiated to acknowledge the association request from the X73 Agent and gets the device profile through context scanner response from the device. Based on the device configuration, the X73 manager starts getting the device data and sends it to data consolidator

Data Consolidator
The data consolidator module is responsible for manipulate the collected data from the devices based on the data type. (For example, the digital data of ECG should get converted into equivalent voltage value to display it in a chart).it also performs the data validation based on the rules defined in XSD's or rules engine. The patient ID will be mapped to the device data during the data consolidation process

Message Store
The device data temporarily stored as flat files to enable consolidation of data and grouping of messages based on devices or patient

Standard Translator
HL7 (Health Level 7) is the standard for the exchange, integration, sharing and retrieval of electronic health information. EMRGateway convert the medical data into HL7 format and send it to various clinical systems.

Configurator
Following are the functionalities provide by configurator module

- UI screens to register Devices, Gateway applications and device association to the clinic/patient
- Patient Information will be manually entered to generate patient Id and associate with respective device/device data
- UI screens will be available to enter the clinical system details, Filter conditions etc Filter

Patient Binder
Many medical devices don't have a provision to enter the patient details. So the association of patientID with the devices is very critical. The Patient Binder module gets the information entered in various Configurator screens, track and associate the patient details into device data during data consolidation and message store process.

Filters
Filter module acts as a Device Observation Filter according to IHE architecture. Clinical systems defines various criteria for medical data collection to each patient.This module is responsible to collect and maintain those filtering details and send it to corresponding modules for proper data consolidation and transfer.

Any of the following Filter Criteria will be defined by each Subscriber

Medical Record Number
Device Class
Update Interval
Patient Location
Parameter Class
Subscription Start and End Times

Subscriber Manager
Subscriber manager acts as an interface between external clinical systems and EMRGateway for data transfer. This component consists of Interface library and registry.Clincial systems can be communicated to the EMRGateway using web services, FTP, wrapper API's or through active-X controls.

Interface Library
This module maintains the interface components for various clinical systems and public data store like Google Health and MS Health Vault servers.

Clinical Systems Registry
The applications, clinical systems which required patient medical data get registered into CS Registry modules. it supports web-based and standalone applications.

Supported Devices
Following are the devices that will be supported by EMRGateway.Based on the manufacturer the protocol and data format will varry.The device manager module will have plug-ins to support all type of devices

Vital Signs or Diagnostics devices, Infusion Pumps, Dialysis devices, Anesthesia machines, EKG and EEG devices, Endoscopy devices, Glucometers, Urimeters, Bedside devices, Oximeters with Patient Monitoring and Alarm Systems, Ventilators, Ultrasound devices, Stress testing devices

Key Features & Differentiator

- Pluggable device-specific interface library enabling easy support for varying device protocol and data formats
- I/O communication over Wi-Fi, Bluetooth, USB, FTP, Modem and Serial port based protocols
- Data format includes digital data(16 bit signed integer/2 byte), .DAT files (compressed flat files) and XML
- Encryption & decryption
- Support for Continua X73 Agent-Manager protocol
- Flexible clinical systems connectivity with system-specific data management interface library
- Enabling unified feed, frequency selection, parameter & unit mapping, unit conversion and data manipulation
- Data format support includes IHE/HL7 v2.x, CCR and Proprietary binary/text
- Clinical Application interface using Socket, FTP, ActiveX and web services
- Automatic device detection, connection and data acquisition without user intervention.
- Notification when device is unplugged or moved away from the radio range and automatic re-connection when device enters the range.
- Support for device enabled events. (Eg: When alert messages sent from the device, low battery, alarm etc).
- Can be integrated with health vault supported devices and upload data to HV server. Similarly can work with Google health.
- Solution can be extended to medical image acquisition and stored in archival server.

The Road forward

The Medical devices practice, Wipro Technologies is proactively working on developing the EMRGateway solution.

The solution is being demonstrated to various medical devices OEM/healthcare customers and thought leaders. This will enable the team get the inputs from the industry which will help refine the final solution in order to address the needs of different OEM's.

Conclusion

The EMRGateway solution would enable patient monitoring devices from different makes to talk to a single application running on a central server in the hospital environment and would communicate with various other hospital/healthcare applications which would use these data for better clinical results.

This would not only enable EMRGateway Application to accurately monitor and collect data from multiple devices attached to multiple patients but also saves lot of efforts of various people involved in managing the clinical environment.

The suggested EMRGateway solution would result in

- Reduction of manual labor for collecting data
- Real time detection of changes in a patient's condition
- Continuous and intermittent assessment of critical physiological parameters;
- Improvement in patient outcomes
- Reduced costs

References

http://www.continuaalliance.org/home
http://www.ihe.net/
http://www.hl7.org/
http://www.ieee.org/portal/site
http://code.google.com/apis/health/
http://msdn.microsoft.com/en-us/healthvault/default.aspx

Acronyms

API	Application Programming Interface
DOR	Device Observation Report
DOC	Device Observation Consumer
DOF	Device Observation Filter
ECG	Electro Cardiogram
EMR	Electronic Medical Record
HL7	Health Level 7
HIS	Healthcare information System
ICU	Intensive Care Unit
IHE	Integrating the Healthcare Enterprise
PHR	Patient Health Record
PCD	Patient Care Data

About the Author

Mohan is working at Wipro Technologies since September 1999 as a Solution Architect. Having 9+ years of experience in J2EE platform and being part of the Medical Devices practice of Wipro Technologies for more than one year. Mohan focuses mainly on eHealth solutions, LIS/HIS/PHR/EMR integration strategy and medical devices connectivity solutions. He is an active member of Continua Technical working group and board member of CSB group of continua. He holds bachelor's degree in Computer science & Engineering.

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