Integrating the Healthcare Enterprise

IHE Patient Care Device (PCD)
Technical Framework
White Paper

Medical Equipment Management (MEM)
Overview and Profile Roadmap
Version 1.0

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Contents

1.0 Introduction

The appropriate management of medical equipment is vital for ensuring safe, effective, timely, efficient, and equitable healthcare, yet management of medical equipment is quickly becoming less effective by traditional methods. Most healthcare delivery organizations (HDO) must manage tens of thousands of medical devices. The management of these devices involves a wide array of activities including planning, procurement, inspection, inventory, testing, monitoring, maintanence, and de-commissioning. Many of these devices are becoming networked, but there are no common standards-based technologies for supporting these device management & maintenance activies. The technology profiles presented here address both the actors and transactions that are required to perform management activites, as well as the basic content that is needed to perform specific tasks (e.g., device identification, or representation of battery charge status).

1.1 Scope

This white paper focuses on how IHE technical frameworks could be leveraged to addresses the management of medical equipment. The intention is to identify some of the current problems and propose technical solutions to these problems.

There are several IHE Patient Care Devices profiles and transactions that could be used to accomplish specific aspects of medical equipment management. For example, the configuration managmenet of medical devices could be addressed within the Device Point-of-Care Integration (DPI) profile. The existing transactions originally created for the Device Enterprise Communication (DEC) profile could be used to report back much of the management information required including device status information. Medical equipment management could also benefit from the transactions exchanged via the Alarm Communication Management (ACM) profile.

While this white paper is deliberately constrained to the managmenet of medical equipment, many of the concepts could be extended to management of other enterprise assets including staff, patients, and laptops. For this reason the IHE IT Infrastructure (ITI), and IHE Patient Care Coordination (PCC) domains could also benefit from this work.

1.2 Goals

This paper addresses the following goals:

- Call attention to the need for a framework to create a standardized management capability for networked medical equipment.
- Detail key use cases that show existing problems that need to be solved.
- Discuss technical approach
- Evaluate feasible implementation timelines for a MEM profile.
- Identify required coordination efforts between standards delivery organizations (SDO's), implementators, and other IHE domains or profiles.

1.3 Overview

This paper presents an overview of the existing problem in healthcare organizations associated with the management of networked medical devices.. Several use cases are presented and analyzed with respect to problems that IHE can help resolve. The resolutions will include proposed new actors and transactions, and where applicable how existing actors and transactions could be implemented to resolve the problems. A reasonable timeline for implementation will be proposed.

1.4 Expected knowledge and references

It is assumed that the reader has a working knowledge of

- IHE and its technical framework organization
- Medical equipment management activities

1.5 Request for Feedback

The IHE Patient Care Device Technical Committee requests feedback on the concepts and technical framework profile supplements described in this White Paper. In particular, we would like your thoughts on whether this paper captures the problem as you see it and what you think of the solution. Comments can be submitted via the web discussion forum at http://forums.rsna.org.

1.6 Open Issues and Questions

Date Opened	Description	Resource

2 Medical Equipment Management

Medical equipment is quickly becoming less manageable by traditional methods. Most healthcare delivery organizations (HDO) must manage tens of thousands of medical devices representing numerous makes and models. The management of these devices involves a wide array of activities including planning, procurement, inspection, inventory, testing, monitoring, maintanence, and de-commissioning. Common activities include unique device identification, ongoing or periodic determination of the device's location, operational status, battery level and charging profile, software / hardware configuration including serial numbers, pending upgrades or software updates, remote maintanence, and risk management.

Traditionally medical devices have functioned as stand alone, or perhaps locally networked without the capability to transmit information outside of their own realm. As more equipment becomes connected to the enterprise network, it would be beneficial to equipment management activities to also be able to use these networking capabilities. Currently there are no common standards-based technologies for supporting these device management and maintenance activies. There are several vendor dependant methods in use across the industry showing that this is possible.

There are several potential benefits of this electronic approach to medical equipment management.

- Increases in patient safety by having safer, more reliable equipment available to clinicians when and where they need it
- Reducing equipment failures through proactive maintanence
- Managing the risk associated with networking medical devices
- Tracking devices
- Making sure devices are configured correctly
- Evidence based maintanence planning could be fully realized with the automated, electronic reporting of maintanence information, this could allowdevices to be scheduled for maintence when they actually need it
- Devices could also be more effectively used requiring less inventory.

3 Use Case Requirements

3.1 Device Configuration Management

3.1.1 Use Case 1

Increasing numbers of medical devices and complexity, along with perhaps increased attention to field problems has led to an increasing number of recalls. The absence of Unique Device Identification (UDI) means hospitals often must use manual and imprecise systems to find and properly identify recalled devices. Implementing UDI in combination with device tracking would potentially increase patient safety and decrease the work load and cost to address recalls.

3.1.2 Use Case 2

Medical devices often require reconfiguration when used in different clinical contexts. For example, when an IV pump is used in the NICU it may require different libraries, alarm settings, and control parameters than the same IV pump used in the OR. Such devices should have pre-programmed or user-configurable profiles based on use-context.

3.2 Location and Tracking Service

3.2.1 Use Case 3

Finding patient care devices when and where clinicians and other personnel need them is crucial to patient care. Tracking devices could provide the ability for clinicians or service personnel to find equipment when they need it, enable usage models, and provide alarms when devices cross boundaries.

3.3 Battery Management

3.3.1 Use Case 4

Mobile patient care devices are often submitted for service due to battery problems, are put on regular maintenance schedules for periodic battery replacement, or batteries may fail prematurely interrupting patient care. Patient care devices using batteries should send periodic power status messages to a management system containing information such as current battery charge level, battery type and installation date, estimated battery life remaining, and current power source status (i.e. currently running on A/C or D/C).

3.4 Operational Status Monitoring and Maintanence

3.4.1 Use Case 5

Today ventilators typically have preventative maintanence (PM) performed every 6 months and as needed because its not necessarily known when a PM is actually required. Awareness of the

need for maintenance sometimes comes too late after a problem occurs or too soon when maintenance is not needed, resulting in extra cost to the organization and/or unplanned loss of availability of the device. Therefore is beneficial going forward for the ventilator to send periodic data back to a computerized medical maintanence system (CMMS) reporting device usage parameters, event logs, and other information required to predict necessary preventative maintenance. The system should have the ability to analyze the data streams to predict calibration problems. The CMMS could automatically generate work orders based on a defined algorithm of the actual use and event logs. The ventilator would also send aperiodic data as it occurs of equipment technical alarm conditions such as loss of A/C power loss, low battery, loss of gas, etc

3.5 Patch Management

3.5.1 Use Case 6

Many patient care devices integrate off-the-shelf (OTS) software such as Linux/Windows/Oracle. The management of devices containing OTS may require periodic installation of patches. Many manufacturers provide field-installable software updates to fix bugs or address recalls. Devices should have the ability to report current software revisions and dates, the source of software, installed patches, and pending patches

3.6 Event Log Management

3.6.1 Use Case 7

When devices fail it is often a cumbersome process to determine root causes. Devices should have the ability to send periodic or aperiodic history to a repository. This would include device event logs, change logs, alarm events, and power/boot-up statistics. There should be a distinction of severity levels of alarm status such as critical calibration errors versus warnings of poor power quality. Reporting should be user-configurable such as reporting warnings as they occur versus send all events once per day.

3.7 Remote Maintanence

3.7.1 Use Case 8

Remote management has been defined as one of several tasks that can be performed on a networked medical device such as system monitoring, software upgrades or other system modifications, look-over-the-shoulder support, and restarts. While sometimes thought of as being a connection to the manufacturer, there are also in-house or other service provider opportunities such as status checks, local drug library updates, and third party service. Remote maintenance offers the opportunity to reduce cost and improve timeliness of service and support. Remote maintenance may also have unique capabilities, such as identifying sporadic problems that hands-on maintenance could not support. In most instances of remote maintenance the key issues are reliability and security of the information exchange, along with controlling access and timing of interventions.

3.8 Risk Management Support

3.8.1 Use Case 9

The draft IEC 80001 requires a life cycle risk management process for networked medical devices that includes not only pre-deployment risk analysis (incl. network configuration
215 documentation) but also dynamic / periodic assessment of network performance and functioning of risk controls. Any set of MEM profiles should provide the information and services needed to support all 80001 activities and documentation that would become part of the organization's risk management file).

4 Technical Approach

4.1 Existing PCD transactions

4.1.1 PCD-01 (Communicate PCD Data)

The original DEC profile was built upon this transaction. It could be leveraged to transmit many of the data elements required to accomplish the workflows in the previous scenarios. For example the battery management scenario would require the following information:

- Current source of power
  - A/C Utility
  - D/C Battery
- Charge level
  - Percent battery capacity
  - Estimated operating time remaining
- Charging / Discharging history
  - Date/time of last charge
  - Charge capacity achieved
  - Last battery run time
- Battery type
- Battery installation date
- Battery life expectancy (days until replacement required)

4.1.2 PCD-04 (Report Alarm Status)

Alarms would be an important part of several of the scenarios presented in this paper. For example in the operational status and monitoring case a device that encounters a non-critical error that should be addressed quickly could be sent via the PCD-04 transaction to a system such as a computerized maintanence managmenet system to generate a work order.

4.2 New transactions

4.2.1 Location Tracking

The location tracking scenarios addressed in this paper would require extensive analysis to find suitable standards that could address the use cases. HL7 v3 has a proposed schema for this topic under the title, “The HL7 Version 3 Standard: Registries, Real Time Location Tracking, Release 1.” This draft comes from the Patient Administration Technical Committee of HL7.

4.2.2 Remote Maintanence

NEMA has published a paper. “Security and Privacy Requirements for Remote Servicing.” This paper outlines methods to reduce the risks associacted with remote servicing in healthcare. It points to the use of ISO 27001 "Information technology -- Security techniques -- Information security management systems – Requirements” to establish proper security controls. A table outlines neccesary technical and organizational measures for both the HDO and service organization that should be put in place. These include:

- policies and procedures
- Authorization to connect
- Proper identification of all service activity
- Audit trails
- Secure, encrypted transfer of patient data

4.2.3 Patch Management

The patch management scenario outlined will require a careful analysis of existing protocols and standards for exchanging these types of information. Open Vulnerability Assessment Languauge (OVAL) is one such standard being adopted by the information security industry. This is scoped for vulnerability assessment so its extension to general software maintanence would have to be analyzed.

5 MEM Roadmap

- **Year 1**
  - Develop white paper
  - Determine scope and phasing for MEM supplements
- **Year 2**
  - Split RTLS into its own profile
  - Develop MEM technical framework supplements that defines actors and transactions
    - Focus on:
      - Battery Management
      - Location Boundary Alarms
  - Detail semantic requirements for MEM profile
    - (Data types, names, value sets)
  - Showcase works in progress at 2010 HIMSS Showcase PCD New Directions
- **Year 3**
  - Publish MEM supplement
    - Ensure these use cases are incorporated into supplement
      - Configuration Management
      - Operational Status and Monitoring
  - Test MEM profile and actors at Connectathon
  - Address change proposals and extensions

6 References

http://csrc.nist.gov/publications/nistpubs/800-40-Ver2/SP800-40v2.pdf

http://www.hl7.org/dstucomments/index.cfm

http://medical.nema.org/privacy/remote.pdf

