

Lowering the Cost of Healthcare from the Inside Out

By

Managing Smarter and Connected Healthcare Infrastructures

Executive Summary

Modern Healthcare delivery has become increasingly reliant on a sophisticated mix of medical devices, technologies and facilities. These include a wide range of diagnostic, surgical and therapeutic systems as well as Life-Safety equipment and facilities in the environment of care.

The proliferation of this indispensable medical technology has created a strain on capital investment and operational budgets for Healthcare providers and hospitals. As a result, providers are looking for ways to extend the asset longevity by managing these assets more efficiently and effectively. Integrated Asset and Service Management solutions can provide greater control and visibility across the multiple asset classes that are available in a hospital environment.

The growth of connected medical assets & systems, and the high volume of multimodal data they generate, has created new challenges for the Healthcare IT organizations and their infrastructures.

In Smarter and Connected Hospitals, the line between different asset classes is blurred. The management of IT assets and networks has become a critical component to the delivery of healthcare. According to the Global standard issued by the International Electrotechnical Commission (IEC-80001ⁱ) *“...IT-Networks are becoming increasingly vital to the clinical environment and are now required to carry increasingly diverse traffic, ranging from life-critical patient data requiring immediate delivery and response, to general corporate operations data...”*

As a result of this convergence, Regulators and Healthcare organizations are increasing their focus on the need for a holistic approach to managing medical assets. This approach would facilitate the management of Clinical & Biomedical, Facilities & Engineering, Electronic Health Records (EHR) & Imaging Systems, and the Health Information Technology Infrastructures supporting them.

This document explores the benefits of managing Smarter and Connected Healthcare operations utilizing a unified approach to Asset and Service Management to administer all Healthcare assets classes with a single solution.



Managing Smarter and Connected Healthcare

To support their mission, Healthcare organizations are managing an increasingly sophisticated mix of devices, equipment and facilities as well as supporting Healthcare IT Infrastructures.

Healthcare organizations managed this sophisticated mix of assets in functional areas including:

- ▲ Clinical and Biomedical
- ▲ Facilities and Engineering
- ▲ Health Information Technology
- ▲ Healthcare IT Infrastructures and Networks

Historically, these assets have been procured, managed and supported by individual departments in a decentralized and standalone manner.

Today, healthcare delivery relies on the consistent operation of assets and infrastructures across the organization. Increasingly, these assets have onboard computing power and networking capabilities. The convergence of clinical, facilities, and IT resources is blurring the line between assets classes and increasing the potential risks for undesirable interference.

The proliferation and increasing reliance on medical technologies has created Smarter and more Connected hospitals. It has also brought forth a new level of complexity and risks. Simply put, interconnected healthcare cannot be effectively managed in stovepipe environments.

FDA's examination of modern medical device networks and computer infrastructures, informs this reclassification of a category of post-amendment computer and software devices that can be regulated under a single classification.

This medical device has been named a "Medical Device Data System" or "MDDS."

Source: Federal Register

IT Infrastructures and Networks have become vital to the collaboration and communication required to provide high quality healthcare services. The US Food and Drug Administration (USFDA) examination of modern medical device networks and computer infrastructures, has led to the classification of most Healthcare IT infrastructure as a Class I medical deviceⁱⁱ. The regulation classifies devices intended to transfer, store, convert, or display medical device data as a "Medical Device Data System" (MDDS) subject to applicable USFDA regulations. According to the Rule, "an MDDS may include software, electronic or electrical hardware such as a physical communications medium (including wireless hardware), modems, interfaces, and a communications protocol."

The growth of this indispensable medical technology has also created a strain on capital investment and operational budgets for Healthcare providers and hospitals. As a result, providers are looking for ways to extend the asset longevity by managing these assets more efficiently and effectively. Integrated Asset and Service Management solutions can provide greater control and visibility across the multiple asset classes that are available in a hospital environment. These trends beckon for an integrated solution to manage all Healthcare IT asset classes.

Integrated Asset and Service Management Systems provide a unified and consistent platform to enable total visibility from multiple sites across functional areas supporting cross-departmental initiatives. The resulting increase in asset and service efficiency can promote improved patient care while managing costs.

The Challenge of Managing Converging Healthcare Infrastructures

Modern Healthcare facilities depend on the availability and use of the clinical and biomedical equipment to deliver patient care. In turn, these rely on the facilities and engineering assets that constitute the environment of care. Consequently, these intelligent and interconnected assets depend on networks and other IT infrastructure that enable collaboration.

The realization that simply managing Healthcare assets is not enough has led to increased activity by regulators, Standard Development organizations and the industry.

Managing “endpoint devices” is no longer enough to ensure patient safety and clinical outcomes.

“...IT-Networks are becoming increasingly vital to the clinical environment and are now required to carry increasingly diverse traffic, ranging from life-critical patient data requiring immediate delivery and response, to general corporate operations data...”

Source: IEC-80001

Interconnected Healthcare requires control over the IT Infrastructure supporting Smarter and Connected medical devices and life-safety equipment.

The issue of interoperability, connectivity and security of underlying IT networks and systems has recently driven a global focus on the management and control of connected Healthcare assets. This is a challenge for the entire ‘ecosystem’, the suppliers of devices and diagnostic equipment, the Healthcare providers, and the networks that are used to connect them.

The management of Medical Assets connected to IT Networks is becoming increasingly vital to the clinical environment. To address this growing concern, the International Electromechanical Commission (IEC) in collaboration with International Standard Organization (ISO) has issued IEC 80001-1 “Application of risk management to information technology (IT) networks incorporating medical devices.” This global

standard provides a framework with defined roles and responsibilities for Hospitals, Medical Device Manufacturers and IT Suppliers to ensure the safety, effectiveness of data and system security.

Compliance with IEC 80001-1 will require that Healthcare providers shift from the traditional stand-alone and silo asset and service management approaches in favor of integrated systems, which provide enhanced visibility and control.

The Joint Commission has also addressed the convergence of Healthcare assets through its Sentinel Event Alert, Issue 42: “Safely implementing health information and converging technologiesⁱⁱⁱ.” The Alert states: “As health information technology (HIT) and “converging technologies”—the interrelationship between medical devices and HIT—are increasingly adopted by healthcare organizations, users must be mindful of the safety risks and preventable adverse events that these implementations can create or perpetuate.”

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Source: The Joint Commission

Conclusion and Recommendations

To support their mission, Healthcare organizations are managing an increasingly sophisticated mix of devices and equipment. The delivery of high quality healthcare is dependent on a wide variety of sophisticated diagnostic, surgical, therapeutic systems, the environment of care, as well as supporting IT Infrastructures.

Healthcare delivery dynamics are driving organizations to seek innovative approaches, which provide the highest quality patient care and improve clinical outcomes while at the same time reducing the overall costs of providing this care. All while ensuring compliance with applicable regulatory requirements.

Financial pressures to manage Healthcare costs call for changing business, technology and regulatory models traditionally used in the industry. Integrated Asset and Service Management solutions can help HC providers improve care while controlling costs.

The growth in medical assets and systems, and high volume of multimodal data they generate, has created new challenges for the Healthcare IT organizations and their Infrastructures. As a result of this convergence, Regulators and Healthcare organizations are increasing their focus on the need for a



holistic approach to manage Healthcare Infrastructures. These trends are driving Healthcare providers to implement a holistic approach to the management their Healthcare Infrastructure.

Healthcare providers would benefit from the use of integrated systems to manage all asset classes with a single solution. This approach would enable real-time visibility and ensure control across all assets in the organization.

Related Reading:

[Integrated Asset and Service Management for Healthcare Providers](#)

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Published April 2011

ⁱ ANSI/AAMI/IEC 80001-1:2010 Application of risk management for IT-networks incorporating medical devices -- Part 1: Roles, responsibilities and activities, October 2010 http://marketplace.aami.org/eseries/scriptcontent/docs/Preview%20Files/80001011010_preview.pdf

ⁱⁱ USFDA Medical Devices, Medical Device Data Systems Final Rule, February 2011 <http://axendia.com/Axendia-FDA-MDDS-Rule-FR-Notice.pdf>

ⁱⁱⁱ Joint Commission, Sentinel Event Alert, Issue 42: Safely implementing health information and converging technologies, December 2008 http://www.jointcommission.org/sentinel_event_alert_issue_42_safely_implementing_health_information_and_converging_technologies/