Viewpoints

Viewpoints on

Digital Thread and Smart Connected MedTech

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Medical device companies face intense and constantly evolving pressures around regulatory scrutiny, product quality and evolving healthcare models. In response, many manufacturers look to digital transformation of the value chain – from product development to manufacturing to service.

The COVID-19 pandemic has both accelerated this digital transformation trend and become a testing ground to validate the processes and technologies companies have invested in.

As we move into the future, companies should look for ways to leverage the digital thread – a seamless flow of data that spans the entire value chain – to accelerate and scale digital transformation initiatives.

The digital thread has great potential to transform the life sciences industry by enabling a seamless flow of data across the value chain, connecting clinical, product development, manufacturing, field service and post-market surveillance data.

However, there are challenges. Digital thread maturity is sporadic, and most companies are generally immature. Many still use paper-based or point systems. Most companies have no overarching enterprise architecture or digital thread roadmap to guide them based on strategic imperatives, compliance mandates and market demands. Others lack governance and rely on uncoordinated skunk works band aids to fix their problems. Rampant acquisitions and divestitures further exacerbate these challenges.

World class companies are already enabling greater connectivity and insights across the value chain, with processes and technology that integrate digital medtech products, regulatory information management, smart manufacturing, field service and advanced analytics to **provide intelligent data to the right functions are the right time.** This creates new opportunities to reduce risk, improve quality, increase service profitability and customer satisfaction, and accelerate innovation.

Now is the time.
Companies that want to remain competitive must move forward on their digital thread initiatives.

Today, more than ever, there are exciting opportunities for life sciences companies to better serve more people around the world with increasingly innovative and affordable diagnostics, treatments, combination devices and cures.

This compendium contains helpful advice on leveraging the power of smart connected products and systems, transforming them with advanced analytics and extended reality (XR) to achieve unprecedented business and patient outcomes across the healthcare ecosystem.

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Digital Thread in Life Sciences: The Future of Product Innovation

by Shamina Merchant, Leo Moran and Dave Hadfield

Our world changes daily in front of our eyes. The COVID-19 pandemic continues to have profound effects on our lives. As we move into a new future, one thing is for certain... the future will be increasingly digital.

The Shifting Landscape in Medical Device

It's clear that pandemic-related challenges will drive lasting changes in the way we all work, especially within industries that are directly affected by the pandemic.

Imagine Susan, a 43-year-old mother of two. She has worked in the medical device industry since 2002 and has experience in various stages of the product lifecycle. Currently, she serves in a product management role and has spent the last two years developing a plan for the next big product for her (fictional) $2.2 Billion medical device company, Kuality Kare.

In March of 2020, the world she knew was turned upside down, and her focus became firefighting through a situation she had not yet had a chance to process. There were a million questions she didn't have the right answer to, and no textbook example to hold up as a leading practice.

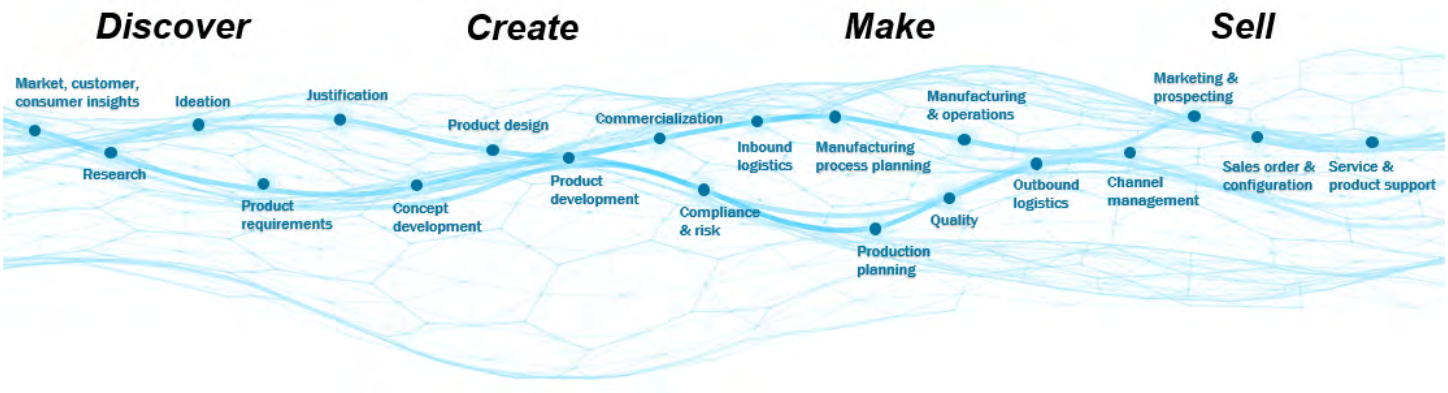
Susan's story is not unique. Companies across the medical device industry were disproportionately impacted due to the pandemic. Early in 2020, as healthcare organizations initially braced themselves for overcapacity, the industry struggled to keep up with the rising demand for essential products while also struggling to adapt to the implications of halting elective procedures. The industry reeled as workforces became

remote overnight. For many, protecting employees came at the expense of effective collaboration.

This not only impacted product development and manufacturing, but sales, training, and product servicing, as much of the industry was underprepared to solve challenges traditionally resolved in person in this new remote working environment.

It is clear that the companies who focused on building their digital capabilities in recent years have had a significant advantage in adapting and responding to the pandemic, but what does this signal for the future?

According to the Harvard Business Review, in 1958, the average lifespan of companies listed in Standard & Poor's 500 was 61 years. By the 1980s it was down to 25 years. Today it is less than 18 years. The reason for the sharp decline? The rate of change in the world has increased dramatically due to digital transformation. Life Sciences organizations must embrace digital transformation if they are to survive in this rapidly changing world.



If the value chain represents all the activities that a company completes to deliver a product to the market, then the digital thread is the fabric that holds it together. The stronger the fabric, the stronger the value chain. The focal point of the digital thread is the digital twin, or the virtual representation of the physical product. The digital twin can be used in design, testing, monitoring, servicing, and other functional areas to augment product management capabilities.

Reimagining Product Innovation with the Digital Thread

To examine how the digital thread enables innovation in the face of great challenges, let's jump back to the present and check back in with Susan and her colleagues at our fictional medical device company, Kuality Kare. In this scenario, we assume they have a modern digital infrastructure in place, and this dramatically improves their ability to innovate and deliver.

KUALITY KARE

Using advanced analytics, Kuality Kare has identified a market need brought about by the pandemic. With minor changes to an existing product, they can help fill this crucial gap. If Kuality Kare can act quickly, it can help the world combat the pandemic and serve shareholders by offsetting lost revenue to their elective surgery products business. Luckily, the company has spent the last few years investing in its digital capabilities, so Susan feels confident in her team's agility and preparedness for this challenge.

Susan's colleague **Bill** is driving new ways of working in product design. He recently led Kuality Kare's shift to cloud-based CAD tools – which integrate seamlessly with their product lifecycle management (PLM) systems – and Bill is especially grateful to avoid the pains that come with traditional file-based CAD systems that limit collaboration. His rapid adoption of game-changing new features – like the ability for his design team to collaborate on the same CAD model in real time – allows them to iterate quickly as they adjust an existing product's design to fill the identified market need.

This CAD model is the basis for the digital twin – a concept that Susan is pushing at Kuality Kare. Digital twins come in a variety of forms, often incorporating several discrete models threaded together. These representative models can be composed to work together, allowing organizations to simulate an object's behavior in a specified digital environment, subject to a known set of assumptions and conditions. Applying physics-based digital simulations feed incredible insights to product design that do not require the time and expense of physical prototype creation and testing.

Susan's intern **Rachel** has set up a demo to show the team how their 3D CAD models can easily be loaded into an augmented reality application, further expanding the use of the digital twin. Rachel explains how this would allow for a virtual product review that leverages the digital twin for an accurate and informed session in which reviewers need only their phone to participate. These models can then be leveraged again later in the product lifecycle to help with sales, training, and servicing.

Key Elements of the Digital Thread

Because Kuality Kare is quite advanced in investing in digital transformation, leaders like Susan know that the strong digital infrastructure will help her team quickly get this new product to market and support patients in crisis.

The pandemic also proved as a testing ground to validate the processes and technologies they have invested in. Today, Susan can reflect upon some key elements for success as her team prepares to release their next product.

Product Development

1. **Foundational PLM Systems** – These foundational systems manage product data across the lifecycle. In Susan's situation, PLM enables their product concept to move into production through an efficient engineering change management process, designed to provide the right information to the right people at the right time. As the product moves to production, sourcing managers can access the BOM in order to communicate effectively with suppliers and ensure that the right materials arrive where and when they are needed. Simultaneously, manufacturing engineers will use the digital twin along with factory simulation tools to prepare for manufacturing at scale.

2. **Extended Reality** – Sales professionals may not be able to enter the hospital, but they can provide a virtual demonstration of the product leveraging the digital twin and augmented reality, so that their customers can assess the product's real-world capabilities. These models may also be used to train healthcare workers in the field without requiring an in-person training session.

3. **Servicing Excellence** – When a nurse realizes that a device is not working properly, it disrupts patient care and needs to be fixed ASAP to treat critical patients. But there are challenges. Devices are in short supply. There's no time to send the product into a servicing center, and they cannot bring in an outside technician. With a digital thread in place, a nurse simply scans a code on the product to connect virtually to a remote technician. The technician diagnoses the problem based on feedback from IoT sensors in the device and walks the nurse through a simple repair using directions relayed in an augmented reality app on an iPad.

4. **Smart Connected Products** – Kuality Kare can run predictive analytics on data from smart devices and alert technicians of devices that are at risk of malfunction before critical issues take them offline. This allows technicians to proactively service the product and reduce downtime. This is made possible by sensors placed in every device that transmit data back to Kuality Kare's IoT Management System. The data collected can be analyzed to uncover patterns and trends, identifying scenarios that accurately predict the next time a product will require proactive servicing.

Manufacturing

Susan has prioritized critical aspects of the digital thread important to her business (and her product development focus) at this time, but she understands that there is more work ahead in Kuality Kare's digital transformation journey.

For the next phase, Susan has the goal of eliminating paper-based tracking systems on the factory floor and has the following digital capabilities on her radar:

1. **Manufacturing Execution System –** The MES is the solution that will help Susan's company digitally manage the production process. It connects, monitors, and controls all physical systems in place for the manufacturing process. An important output of this system will be the Device History Record that proves Kuality Kare correctly applied quality controls throughout production and conforms to regulation 21-CFR-820.

2. **Industrial IOT –** Working with manufacturers to enable IIOT can help Kuality Kare 'get smart' about the manufacturing process. With sensorization, Kuality Kare can monitor the production of equipment and find ideal operating conditions to increase production yield. Other opportunities include optimizing energy consumption at the asset level and using edge analytics to improve quality control.

One thing is certain to Susan – the many capabilities the digital thread provides to Kuality Kare add up to a sizable advantage that will help the company manage the current crisis while building more resiliency as they prepare for the future.

The Prescription for Digital Thread Success

Unanticipated disruptive events like COVID-19 have made the digital thread more important than ever. The challenges faced as a result of the pandemic serve as a call to action for the life sciences industry to invest in its future, but the path forward is still not clear.

How can organizations move from their deeply entrenched legacy systems to a state-of-the-art digital ecosystem? More importantly, how can they train their people to embrace and make use of these tools?

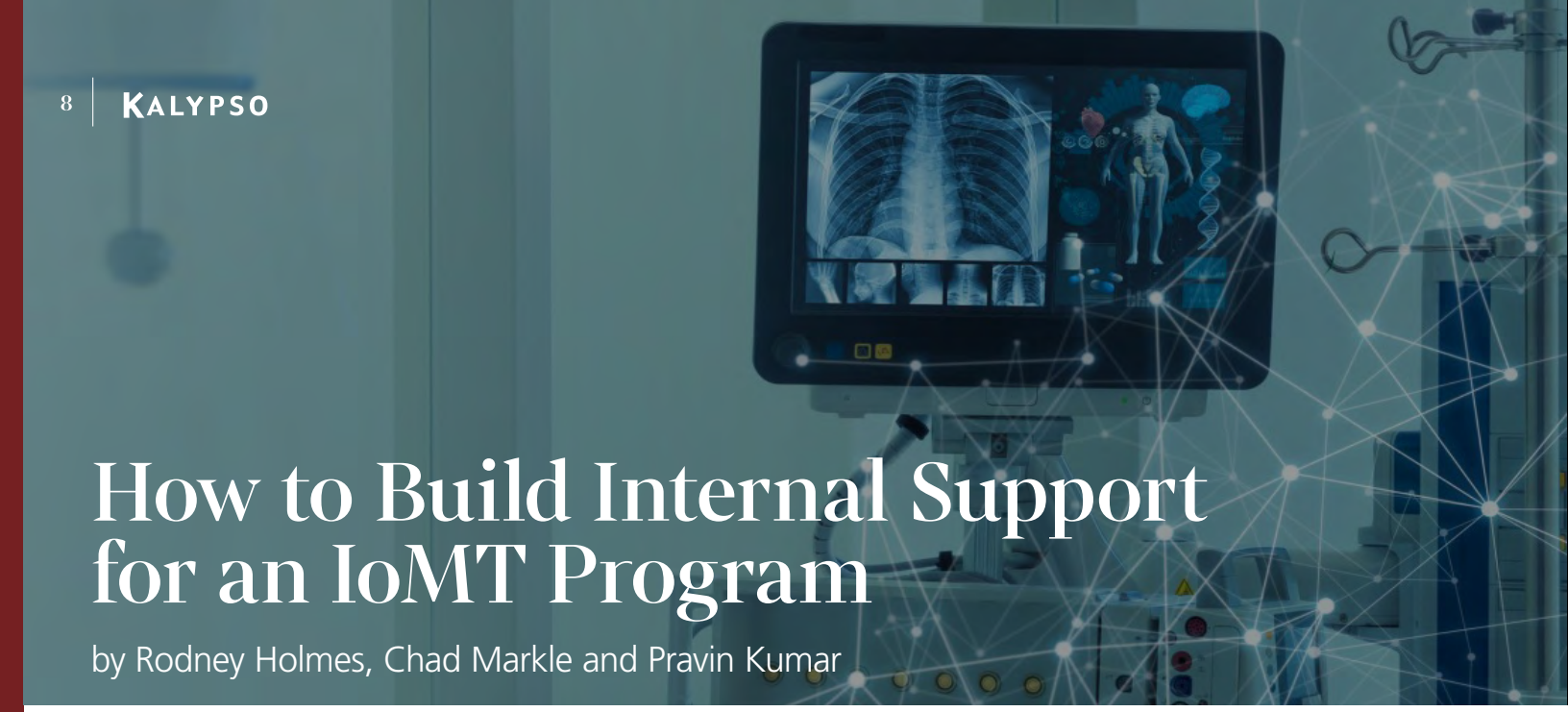
Here are some basic tips for implementing the digital thread and digital twin successfully.

1. **Don't worry about perfecting the digital transformation roadmap.** Instead, we recommend a simultaneous, dual-pathway approach. On the first path, define an overall direction for where you want to go, with a high-level view of systems and connections. Consider separate roadmaps for aspects of digital transformation, like data management, smart connected factories, and smart connected products. Revisit and adjust every 6-12 months based on learnings or business changes. The second path should focus on tackling important current business problems leveraging new and emerging technology. This extremely agile path puts out current fires while not compromising longer-term planning.

2. **Don't focus on technology (and proofs of concept that demonstrate technology).** Focus instead on creating digital proof points with measurable business value. Think about the application of the technology, and the purpose and value of solving a particular business challenge to drive big impact. For example, don't demonstrate augmented or extended reality technology. Instead, demonstrate the ability to operate a surgical robot remotely or to conduct training remotely with the goal of limiting physical presence in hospitals during a global pandemic.

3. With an initial digital strategy and proof points established, next **define the capabilities the organization needs to have the greatest business impact.** This is a combination of people, process and technology that will support an actual digital transformation that is sustainable and scalable, no matter what the future brings.

Susan has done a lot of this work already. Her next step will be to seek ways to extend and build value across the value chain – both within Kuality Kare and to the value chains of suppliers, distributors, and customers. Although Susan's story is fictional, companies that follow her example will reap the benefits now and position themselves to continue to outpace the competition.



How to Build Internal Support for an IoMT Program

by Rodney Holmes, Chad Markle and Pravin Kumar

Healthcare is transforming as Internet of Things (IoT) technology advances and smart connected products are deployed into the hands of doctors, nurses, field technicians, caregivers and patients. This transformation has carved out its own subset of IoT, known as the Internet of Medical Things (IoMT).

The Internet of Medical Things (IoMT) brings together smart connected medical devices, advanced analytics and people (healthcare professionals, caregivers and patients). It's the network of a multitude of medical devices connected by communications technologies. When implemented correctly, the IoMT results in systems that can monitor, collect, exchange, synthesize and deliver valuable new insights like never before.

The IoMT provides a more coordinated, connected healthcare system where technology empowers providers to deliver better care to patients throughout their health journey and where better patient outcomes are delivered at increasingly lower costs.

But how do you get there? The opportunity is huge, and there are many potential starting points. If you're involved in medical device field operations and are responsible for IoMT strategy, we've got your back. Here's our advice for building a business case for IoMT initiatives, based on our experiences at the top medical device manufacturers in the world.

Four Essential Elements to Building Internal Momentum

Taking full advantage of all that IoMT has to offer requires changes in the way stakeholders use, manage and maintain smart connected medical devices. Unfortunately, large-scale change efforts fail more often then they succeed. So what distinguishes IoMT programs that have tremendous success? There are four essential elements.

1. **Tell a Compelling Story**

   First is a compelling story, because stakeholders must understand the rationale for IoMT and embrace it. One of our clients focused on communicating service response times and planned improvements; another focused on being a market leader with a modern servicing platform for a smart connected surgical robot.

2. **Role Model Desired Behavior**

   Next is role modeling, because stakeholders must also see leaders and colleagues they respect operating in new ways with IoMT. One Kalypso client used customer testimonials from a highly ranked hospital describing the results they saw from IoMT as a way to help encourage other customers in their adoption process.

3. Create Supporting Mechanisms

Third is supporting mechanisms, because processes, roles and incentives must be in line with the new IoMT program. A leading medical device company worked with Kalypso to create personas for each stakeholder in their IoMT program and then revised workflows to take advantage of new IoMT value.

4. Build New Capabilities

Finally, new capability building is required, because stakeholders must have the skills required to embrace the IoMT operating model. Companies we work with that leverage our compelling IoMT training and education, and that take ownership of the ongoing training requirements, always end up stronger and more capable.

As with any transformational initiative, the move to the IoMT has huge benefits, but many potential challenges along the way. With so many considerations, including infrastructure, interoperability, data privacy and security, it can be easy to lose sight of the bigger picture.

At the heart of this transformation is the desire to improve patient care. Companies that invest time and effort to build internal momentum will move faster and achieve much greater success.

Solution Architecture Strategies for IoT in Medical Devices

by Wayne Posner and Jordan Reynolds

Implementing an IoT solution can be a challenging initiative. Implementing an IoT solution within an industry bound by numerous rules, regulations, and restrictions can add significant levels of complexity.

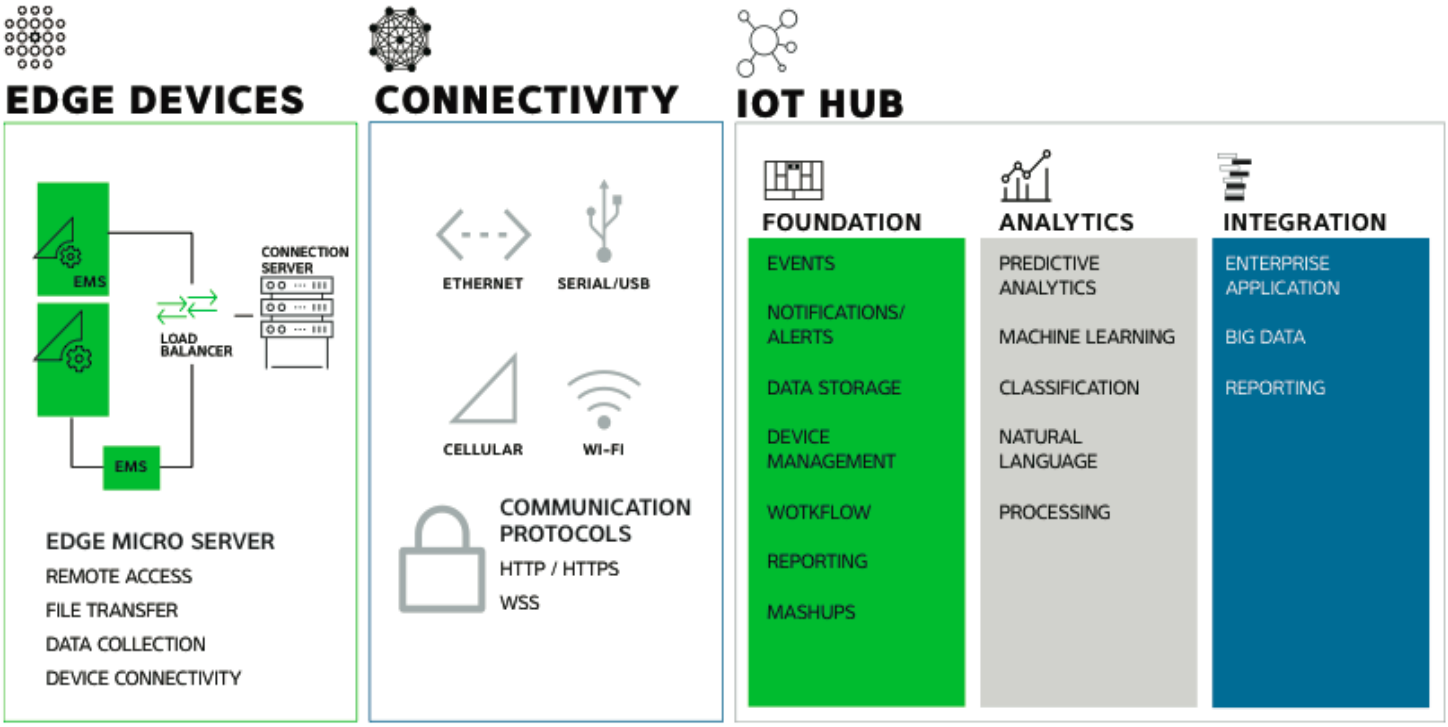
Fortunately, with a well-planned and carefully architected solution, an IoT initiative can be designed to work within the rules and regulations. This means that businesses, such as those within the medical device industry, can begin to realize the enormous benefits gained through this transformative strategy.

IoT Architecture

IoT solutions are generally defined by a three-tier architecture including:

- Private/public hosted IoT hub software solution, responsible for managing data received from remote IoT-enabled physical devices
- An edge gateway, to enable communication between the physical devices and the IoT hub
- Physical (edge) devices

Depending on the scale of the IoT implementation, there may be other architectural components such as load balancers and connection servers.



Medical Device Architectural Considerations

Within the medical device industry, there are additional architectural considerations.

- Does the device store patient data or can patient data be derived from examining device log data? If so, HIPPA compliance is a factor and must be addressed.
- Are there any legacy devices lacking networking capabilities?
- Does the environment in which the device is utilized implement any sort of network? If so, are there network security restrictions that preclude the device from connecting to the network?
- Are there government regulatory export restrictions that limit how where device data can be accessed? If so, a federated architecture with user location based security must be considered.

Security and encryption is always a key architectural consideration for any IoT solution. Many companies have strict constraints restricting specific data to users within specific organizations. Files transferred between the IoT hub and remote devices should be protected by strong encryption algorithms compliant with FIPS 104-2, while in flight, and validated against at least a CRC-256 checksum (SHA-256 hash is preferred), while at rest, to ensure malware has not been introduced.

Most medical devices deployed within a hospital environment are currently restricted from operating in an "always on" connectivity state. These devices operate in an "offline" mode. Working with these devices is a manual process. The typical use case for communicating with offline medical devices is that a qualified and/or authorized user will physically establish a connection between the device and a laptop or tablet.

The laptop or tablet will allow the user to interact with the device data using custom software. Finally, the laptop or tablet will sync the device data with a custom server solution once it establishes network connectivity.

IoT Solutions for Medical Devices Operating Offline

How can an IoT solution help to optimize this type of manual process? There are three possible solutions that work within the confines of devices operating in an offline mode.

Embedded Edge Micro Server

Install an edge micro-server directly on the device, provided the device has built-in networking capabilities; when a connection is required between the device and the IoT hub, temporarily enabling network connectivity is the only requirement. This solution is the most ideal and requires the least amount of customization; however, network security protocols must allow for medical devices to temporarily establish network connectivity when necessary.

Attached Edge Micro Server

Install an edge micro-server on a computer that is always connected or can quickly be connected to the device via a serial or Ethernet connection. Some medical devices may lack network connectivity or the additional resources required to run an edge micro-server, or may not run an operating system compatible with micro-server frameworks such as Java, C, or .Net. A small computer running Linux can be used to host the edge micro-server and establish a serial connection with the medical device. Like the first solution, network security protocols must allow for this computer to temporarily establish network connectivity so that it can communicate with the IoT hub.

Custom Software

Create/Update custom software running on the laptop and/or tablet to enable it as an edge device that communicates with the IoT hub while also adding enhanced cache management functions. This allows the IoT hub to automatically receive cached data from the laptops and tablets (with an active network connection) and push updates down to be cached until the laptop and/or tablet reconnects with the device. Of the three solutions, this is the most complex and time intensive due to the amount of required programming.

Implementing a robust and scalable IoT solution requires a well-planned and thoughtfully designed architecture. Highly regulated industries such as Medical Device have additional architectural requirements to be considered. Through careful design and thoughtful understanding of the governing rules and regulations, it is quite possible to introduce devices that regularly operate outside the IoT paradigm as part of an enterprise IoT solution.

Securing the IoMT – Nine Strategies You Can't Afford to Overlook

by Bryan Kissel and Chad Markle

The headlines are full of stories about companies that fail to live up to the expectations and legal obligations of information security. Compliance is complicated, and it changes a lot.

For medical device companies with an Internet of Medical Things (IoMT) strategy, it's even more complex. Combine recommendations and frameworks like ISO 27001 and the PCI DSS with regulations like HIPPA, GDPR and MDR, and the magnitude of the challenge becomes very clear.

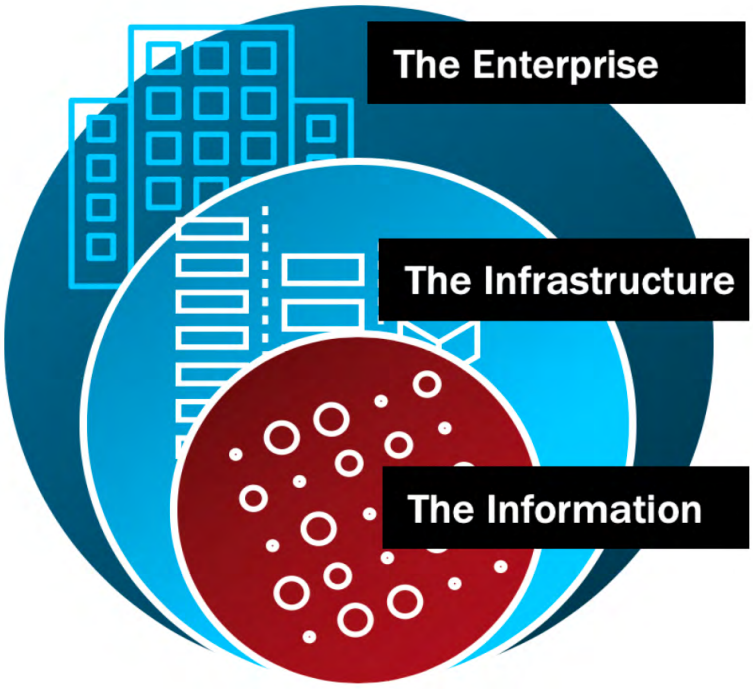
Companies are tasked with protecting both the connected devices in the field and the data they generate and transmit. So today's compliance strategies must include risk-based security practices protecting sensitive data and communications-based compliance practices around reporting, recording and archiving sensitive data.

Protecting devices in the field requires an innovative approach to comprehensive information security, along with compliance practices that can evolve alongside changing formfactors, design principles, connectivity solutions and management strategies. And on top of all this, interoperability and legacy device support is an ongoing, pressing need.

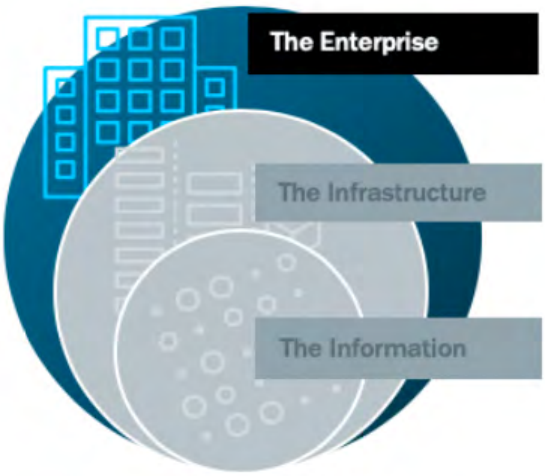
Nine Strategies to Secure the IoMT

When physical security experts secure a house, they think in terms of concentric circles. The tree line or fence would your outer-most ring - whatever constitutes the perimeter. Next would be the front door and anything on the inner-perimeter, like cameras, a storm door or window locks. The inner-most ring would then be a panic room or secure space within the home. Each ring poses a more significant barrier than the last until you ultimately have your human assets within the inner-most ring protected by the increasing degrees of scrutiny as you move inward.

IT and Security professionals should approach security in much the same way. As you move closer to the center of the concentric rings, security controls should become increasingly strict, impeding risk vector access within each ring.



Securing the Outer Ring (The Enterprise)



In the outer-most ring is the true first line of defense – the policies and education practices of the enterprise. Enforcing strong, secure policies should be a part of any company's DNA, but here are a few strategies that must apply to this ring.

1. **Use 'exceptionally' strong passwords**

   Eight-character passwords and mnemonic devices have led to many breaches, and most incidents are still user-related. Phishing, weak credentials and lost devices… we can do better.

2. **Avoid common, shared accounts**

   Shared access, passwords on Post-It notes and 'admin/password' accounts represent the old ghosts of information security risk management. Don't sacrifice security in the interest of deadlines or ease of use.

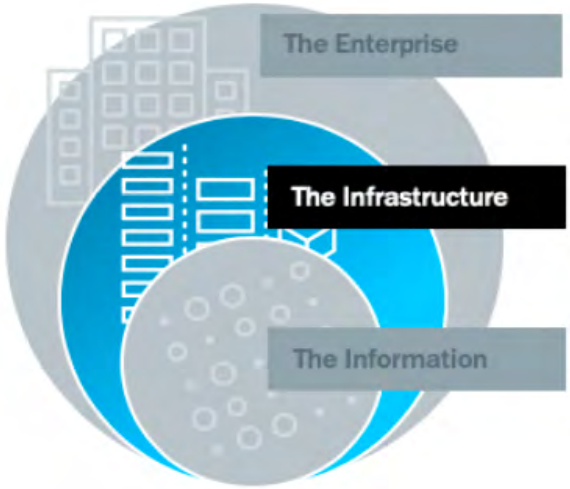
3. **Have a Data Privacy Officer (DPO)**

   Some companies try to put DPO responsibilities on the CISO or a System Admin, but there's enough strategy, policy and education required to justify this role. Plus, GDPR actually requires businesses to have a named DPO responsible for managing Personally Identifiable Information (PII) and protected health information (PHI).

4. **Enforce education, policy and values**

   Educating the workforce must evolve to create a culture of compliance at every level of operation. A clean desk policy is no longer enough, and users that access data in any form have a duty to protect that data and use it appropriately. The enterprise (led by the DPO) must deploy strategies that educate the workforce, monitor for user compliance and report incidents in real-time.

Securing the Inner Ring (The Infrastructure)



The inner ring represents the infrastructure – the hardware that supports applications and devices, secures pathways and manages traffic to assets. Innovation in this ring is critical to the longevity of connected medical devices and the operability of legacy devices still in use. There are many security strategies that apply specifically to this ring – here are some of the most important.

5. **Innovate encryption strategies for micro-formfactor devices and implantables**

   Some of the most common medical devices, like implants and wearables, are the most vulnerable. Tiny Encryption Algorithms (TEA), system-derived passwords and self-encrypting devices are some options on the bleeding edge of device security, since many of these devices are too small to handle large encryption schemes.

6. Encrypt all the blind spots on the information superhighway

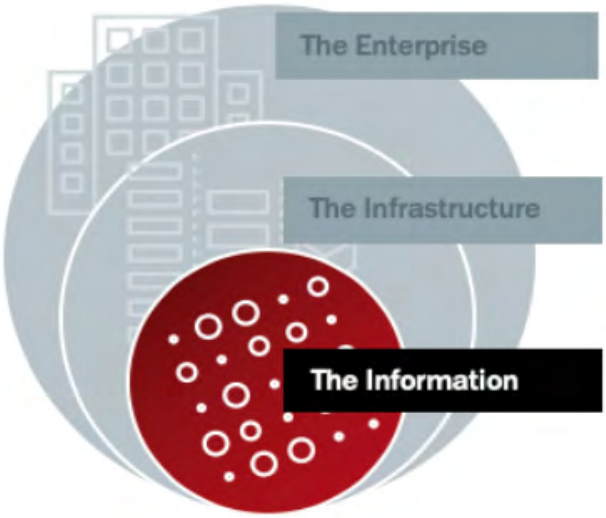
As more and more industries move toward cloud-based solutions and services, data managers must ensure that data is fully protected at every point in its lifecycle. Each system, node and relay must be demonstrably 'as-safe' as the last, from end to end.

7. Secure development of the entire IoMT ecosystem

A secure network or secure out-of-the-box solution is insufficient today. The complete ecosystems that support devices must be implemented with mature information security policies, governance, role-based access controls (RBAC) and deep documentation to ensure compliance across operational regions. Design with security in mind to always be 'audit-ready.'

Securing the Center Ring (The Information)

The center ring protects the most important asset at the heart of the IoMT – the data. Security at this level should be a nearly impenetrable shield of role-based access, attribute-based asset control, data type-specific archiving and retrieval, and comprehensive records retention.



8. Evolve and mature records management practices

Identifying and organizing data is the first and most important step to achieving compliance in any regulated industry. In the US, companies are tasked with securing data according to the risk associated with a breach. Considering the life or death implications of some connected medical devices and the truly personal nature of the data these devices generate, the medical device industry should expect the highest degree of scrutiny from auditors, legislators and even patients. New practices for records management – including documenting design, solution, architecture and audit materials – allow the DPO to demonstrate a reasonable and proactive approach to data security and privacy that lays the foundation for achieving compliance.

9. Manage the data like the high-value asset that it is

Insights gleaned from advanced analytics are the main ROI opportunity. To capitalize on this, data must be managed as a high-value asset. Protected health information and personally identifiable information should be considered as precious as secret business data, proprietary CAD elements, or IP.

In the age of Ransomware and PHI sales on the dark web, the question is no longer when a breach will occur, but how much an eventual breach will ultimately cost. As the IoMT evolves, isolated information security practices are a liability. Interoperability and security practices must extend to every point of the data lifecycle and be capable of growing alongside a maturing and ever-changing device landscape. As data privacy and information security continue to become almost inseparable, the offices of the CISO and DPO must evolve together, presenting a unified front against digital threats and a cooperative partnership in support of audit and compliance operations.

As medical device companies build and evolve an IoMT strategy, these efforts can help minimize risk while fostering a culture that mitigates information security risks, improving overall operational effectiveness, compliance posture and audit readiness.

New Frontiers for Medical Device PLM Systems: Leveraging the Power of Machine Learning

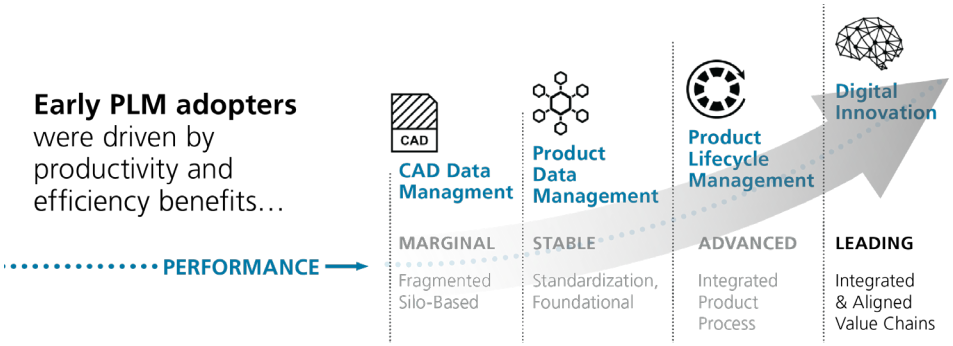
by Dave Hadfield and Jordan Reynolds

Medical devices are essential to our modern society. They give us healthier, more productive, and more independent lives. But the companies who make them face many headwinds; adhering to strict regulatory standards, proving that their benefits outweigh risks, and achieving efficacy and safety standards. To succeed, they must constantly innovate, drive down costs and navigate complex regulatory pathways.

All of this has been the driving force for medical device manufactures to automate and integrate disparate engineering, quality, regulatory, manufacturing and post-market capabilities into a single consolidated product lifecycle management (PLM) system.

Building on a PLM Foundation

Adopting PLM remains a missed opportunity for much of the medical device industry, with the potential to drive long term transformational success. But we're rapidly approaching a time when PLM alone is not enough.



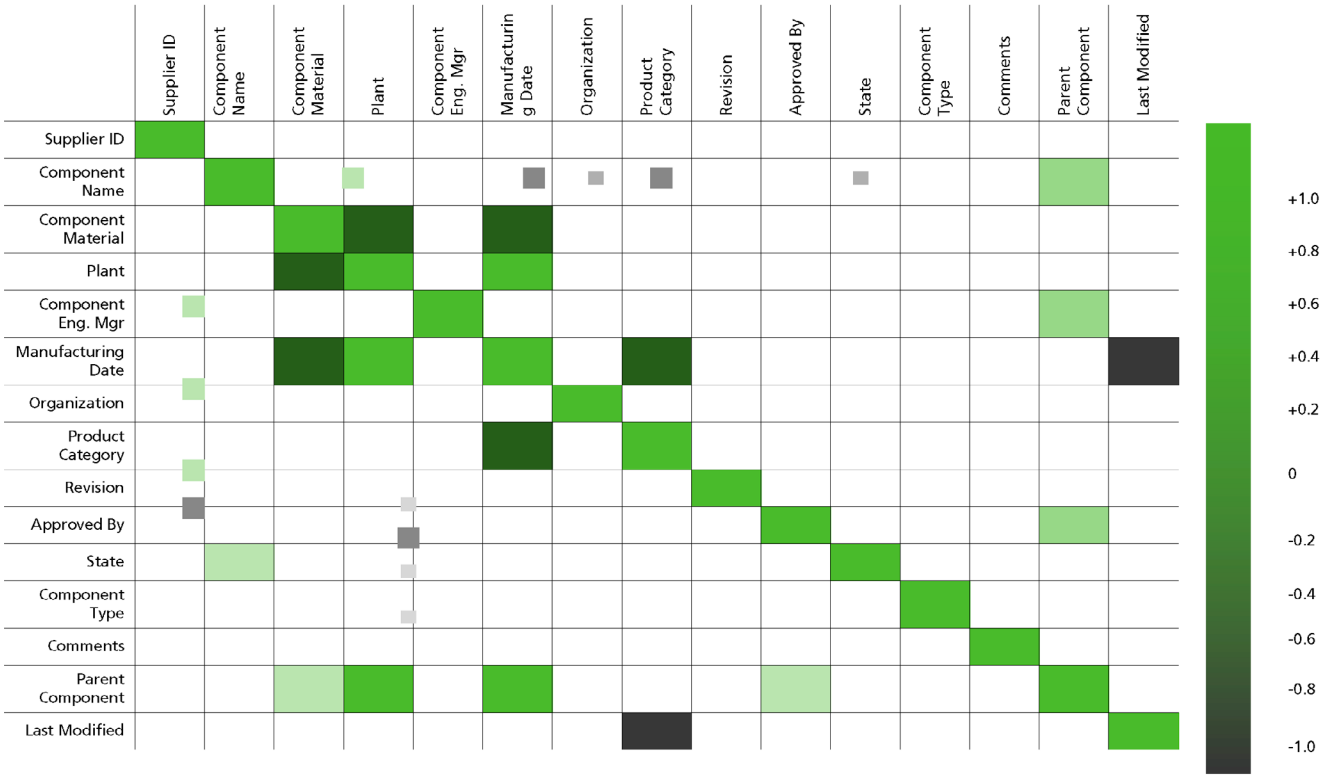
The product lifecycle is captured as data – including at its heart, a three-dimensional math-based model of the product. Companies can extend and gain new insight about these product models using new digital technologies, including machine learning, the Internet of Things (IoT), and augmented reality. These technologies have made extraordinary progress in the past few years. By evolving PLM to embrace digital tools, companies gain strategic insights while facilitating the creation of breakthrough products and services.

Machine Learning and PLM

In a typical medical device company, research, engineering, quality engineering, supply chain, operations planning, and post-market surveillance activities produce large sets of structured and unstructured data. Intersections of those data sets can produce over 750 potential points of data correlation. These large, complex, dynamic sets of data are exactly what machine learning analytics algorithms were built for. Any large, mature PLM system with robust processes and data has almost countless applications to drive value from machine learning techniques.

Potential Applications of Machine Learning to PLM

Apply Machine Learning to PLM Data to Improve Product Development Results



PLM provides the potential to gather large amounts of structured product data, and integrate it with data about post-market quality issues. This gives valuable information to improve products, accelerate the resolution of issues and improve quality outcomes.

But even with advanced integrated and automated processes, it's not easy to identify potential correlations across multiple related data sets. With machine learning performing advanced analytics on PLM data, companies can predict outcomes and improve product development results by understanding the causes behind non-compliances, problem reports, product failures and quality issues.

Understand the Nature of a Product's Evolution using Natural Language Processing

Any given product may go through thousands, even tens of thousands, of iterations with each change recorded in PLM. By parsing language inside changes (tapping into the same type of technologies that make Siri and Alexa successful), we can understand the historical nature of product improvements and draw insight. This can be helpful in new product development efforts, shaving off design cycles and driving innovation.

Find Winning Product Features

What conclusions can we draw from on market sales to identify correlated user experiences? By combining part sales information (say by region) with PLM feature information, we can zero in on market success and tie it to specific product attributes.

Suggest Parts without a Search

Use machine learning to suggest parts based on specification data, and present them to the user. This is similar to how Google Search works when you enter a search term. But this goes beyond search and uses machine learning to identify potential candidates.

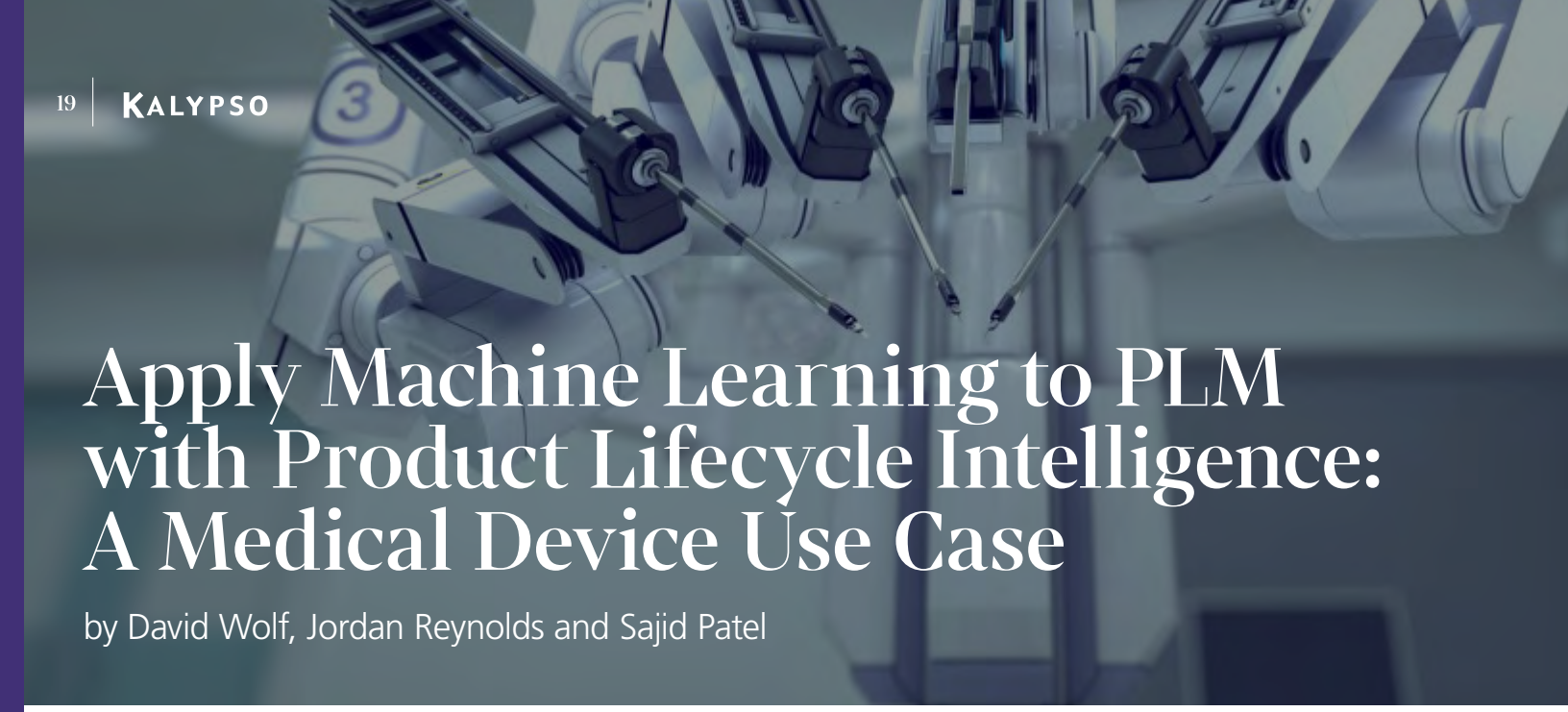
Drive Lean Processes

The system can learn process and corresponding workflow behaviors over time and by user, site, division, product, etc. From this it can identify points of delay and recommend potential process optimizations. Combined with flexible PLM applications, users can apply optimizations that are sensitive to cultures, locales, product types or even individuals to help processes like change, New Product Development (NPD) and Corrective and Preventive Action (CAPA) run more effectively.

Think Forward. Act Now.

Medical device companies have unique challenges. As they strive to differentiate themselves with new and innovative products, they can get benefit from a strong PLM foundation. With PLM, medical device companies collect large quantities of diverse data as they develop products. But PLM alone can't provide true insight from this data.

To accelerate results in a digital world, medical device manufacturers need to think forward and act now. Those who identify opportunities to apply machine learning and advanced analytics to PLM will unlock new insights to outpace their competition.



Apply Machine Learning to PLM with Product Lifecycle Intelligence: A Medical Device Use Case

by David Wolf, Jordan Reynolds and Sajid Patel

Worldwide regulations are changing at an alarming rate. One way for global medical device manufacturers to remain competitive is by optimizing change notice lead times. Today, the ability to apply machine learning to Product Lifecycle Management (PLM) systems can help them better understand and drive insights from product data that has been collected over many years.

Product lifecycle intelligence (PLI) is an evolution of PLM that applies artificial intelligence and automation to help PLM users extract meaningful insights from product data, formulate predictions, recommend improvements, and automate actions within systems and processes.

The potential value is immense because with PLI and machine learning, medical device manufacturers can proactively prevent delays and failures.

This article details how one manufacturer addressed their global challenges with a unique three-phase approach, driving measurable business results.

The Company and the Business Challenge

A top medical device manufacturer wanted to enhance transparency of the change control data stored in their PLM system. The process required a transformation to how they aggregated and displayed data such as aging and cycle time throughput. The organization used PLM dashboards, spreadsheets and shared hard drives to analyze their change control data; a process plagued with common data replication issues. The problem was intensified by the fact that there was no easy way to perform analytics on data without a massive effort and an extensive approval process - which is typical with traditional Master Data Management (MDM) and Business Intelligence (BI) solutions.

Although PLM systems store change data that may be used for auditing purposes, the core platform does not provide advanced analytics capabilities – like machine learning – that can aid in predictive analytics, root cause analysis and discovery activities.

The company decided to execute a proof of value with a role-based application that used a state-of-the-art app to aggregate data and optimize change notice lead times. Just like many medical device manufacturers, the company hoped to optimize their change management process and predict the likelihood that a product would fail or succeed in production.

A Strategic Three-Phase Approach

To address the challenge, the company used a strategic approach based on Kalypso's hands-on experience helping global medical device organizations benefit from emerging technologies. The three-phase

approach is designed to drive maximum value from digital initiatives both in the near-term and for future growth, with an iterative crawl-walk-run cycle.

Phase 1: Start with a Proof of Value Workshop

This phase starts by defining a small scope of business objectives (engineering change cycle time, rejection/rework rate, etc.) The company provides data extract from PLM and Kalypso demonstrates a high-value use case leveraging PLI to drive insights from the data. With a clear link to a strategic business objective, it's easier to show results that help obtain executive sponsorship for the next phases.

Phase 2: Test a Minimum Viable Product (MVP) Pilot in Production

This phase builds on insights generated from connected systems, leveraging machine learning and artificial intelligence to proactively predict and prescribe actions that prevent future crises.

Phase 3: Scale Pilot to other Business Units and Manufacturing Sites

In this phase, knowledge is transferred from the first two phases, enabling multiple use cases, while leveraging medical device connectors, role-based apps and advanced analytics. It is the phase at which the enterprise-wide business value is realized, and the benefits of a strategic digital program start to accrue.

Phase 1 Results

In less than six weeks, Kalypso addressed phase 1 with a medical device role-based app solution using the ThingWorx platform to capture and aggregate real-time data related to the change management process. An analytics engine was used to create a change management algorithm, providing immediate insight into lead time variation within the product and proof of value for leadership support.

This is just the start. In addition to optimizing cycle time, PLI can predict the rate of approval from the implementation board based on the tasks and rework cycles within the change implementation plan.

The company could reduce costs from poor quality through the ability to simultaneously optimize cycle time, streamline the change process and remove bottlenecks before they occur. As a result, the company could expect to provide consumers with a safer and more effective products, resulting in positive brand reputation and increase in market share.

It's important to recognize that using machine learning with artificial intelligence allows an effortless change management process, significant error-reduction and protection of data integrity.

Mergers and acquisitions are commonplace in the medical device industry. For this company, ThingWorx smart connected systems and PLI can eliminate siloed environments, secure data and help prevent quality events.

Maximizing the Value of PLM

PLM can do a great job of managing product data through rapid change, but it's not perfect at putting that data to work through datamining and analytics. For many discrete manufacturers, this means they are sitting on months or even years of untapped R&D product data. By combining PLM with product lifecycle intelligence, companies can bridge the gap in PLM analytics capability today, allowing them to understand current performance, historical averages, and the variances across different business units and functions.

These insights can help them develop more meaningful customer experiences, while driving business and product value. As an organization iterates through product development efforts, their database grows to be robust and the value of PLI grows accordingly.

Companies that continuously strive to maximize the value of PLM – by pursuing PLM system consolidation, looking for more opportunities to leverage insights from data using PLI, and expanding the use of apps to augment consolidation strategies – will continue to expand the return on investment.

Digital Service Transformation: Shift Service from a Cost Center to a Differentiator

by Venkat Gopikanth, Rodney Holmes and David Comerford

While companies have turned to digital transformation to discover, create, make, and sell better products, service has traditionally been an afterthought. In pursuit of getting the biggest bang for their buck with digital investments, companies have placed ***more*** focus on use cases enabling them to deliver new and innovative products to market faster. ***Less*** attention has been placed on service models, which many companies look at as a cost center.

For Original Equipment Manufacturers (OEMs) that manufacture complex capital equipment that sits in a hospital, manufacturing plant or other industrial setting for multiple years, optimizing the way those products are serviced, updated and upgraded can actually be a competitive differentiator.

Service optimization re-invents traditional service roles and processes with remote service, advanced analytics, and extended reality (XR). This portfolio of innovative solutions spanning people, process, data and technology comes together to increase operational effectiveness and create strategic product differentiation, (as shown in the graphic on the right.)

Operational Effectiveness

Reactive → ***Proactive***

On Site → ***Remote***

Blind → ***Data Driven***

Historic → ***Present & Future***

Strategic Differentiation

New Product Sales → ***Products as a Service***

Break Fix → ***Performance Based***

Equipment Uptime → ***Operation Optimization***

Product Value Chain → ***Customer Value Chain***

Throughout the rest of this article, we will discuss how to create step change in your service model be exploring three "how might we" questions.

1. How might we transition from on-site service to remote monitoring and maintenance?
2. How might we equip service providers to deliver superior outcomes when full remote servicing is not an option?
3. How might we measure and continuously improve service models with data-driven insights?

How might we transition from on-site service to remote monitoring and maintenance?

The earlier an OEM can identify equipment issues the better equipped they will be to drive business value for their end users. This means equipment uptime will be the new key performance indicator (KPI) customers use to evaluate OEMs and the equipment they sell.

A digital twin of a product—which is a virtual representation of a product with real-time data—allows OEMs to provide proactive and value-added services to address equipment uptime. Depending on the product and digital twin sophistication, a remote service model may include remote access, software content management and predictive maintenance.

Remote Access

Companies that manage and service devices remotely to meet customer demands for quick responses and service-level agreements (SLA's) while maintaining equipment uptime. Digital twins with real-time data help elevate the services model with expert remote assistance and/or by enabling over-the-air software updates and predictive maintenance.

For example, a leading medical equipment manufacturer has tens of thousands of instruments with embedded software deployed globally in hospitals and clinics. With the onset of a new disease, these instruments will require updates to test for new-to-the-world antibodies. In order to quickly and efficiently deliver these updates, as well as limit exposure of field service technicians, the updates need to be delivered remotely and over-the-air (OTA).

Demand for OTA software also stretches beyond COVID-19. Pressures to introduce new features or functions, patch bugs, apply additional security measures and maintain compatibility with other devices, software, and operating systems were also drivers behind this medical equipment manufacturer's investment.

Over-the-Air Software Updates

Most connected devices today run some form of operating system and software. There is no doubt that most devices will last longer than the version of software they were provisioned with, and there will be security patches and bug fixes along the way. Over-the-air updates create packages to address these issues for immediate deployment or at a scheduled time in the future.

Predictive Maintenance

Predictive maintenance techniques can monitor and analyze device properties to identify potential problems before they cause a shutdown. This can also reduce maintenance costs because maintenance can be performed when it is needed rather than simply scheduled.

The strategic implementation of remote access, over-the-air software updates and predictive maintenance drives many benefits, including:

- Reduced costs and risks associated with on-site service – up to 83% less time on-site
- Reduction in unplanned downtime – up to 30%
- More effective preventative maintenance – up to 47% [1]

1 Connected Field Service Productivity | Improve First-Time Fix Rate | PTC

Even before 2020, market expectations for service in a digital age were transforming. The COVID-19 pandemic has introduced new operating constraints that have accelerated both the expectations and the transformation. Companies must reduce COVID exposure to protect field service engineers and customers.

It's intimidating to re-evaluate and change service protocols, but today's real-world health risks demonstrate the value provided by any extra level of protection.

Despite the move to more remote services, some level of on-site service will remain a constant for the foreseeable future—while the challenges of on-site service continue to evolve. This brings us to our next question.

How might we equip service providers to deliver superior outcomes when full remote servicing is not an option?

Aside from the already massive operating constraints of the "new normal," service calls and visits have already become more complex as assets with more technology elements are deployed at customer premises.

These new complexities have increased the need for holistic solutions that bring together real-time information, dynamic visualization capabilities and remote support. We consider the application of these solutions through two primary lenses—the field service technician and the end user or customer.

Field Service Technician Enablement

Ensure that those in the field have the right tools, expertise and support while on the job. Employ XR technologies, such as augmented or virtual interactive experiences, so on-site personnel can benefit from XR-enabled training before the truck rolls and remote experts can extend expertise to boots on the ground.

Enabling field services teams this way increases knowledge retention through visual representations of complex processes and equipment. It can also provide on-demand expertise through remote assistance via tablets or devices in certain scenarios.

As an example, Xerox has taken a holistic approach to enabling experts, field service technicians and customers. They use augmented reality (AR) to connect field engineers and customers with experts instead of providing service manuals and telephone support. From a field engineer perspective, this led to 67% and 20% increases in first time fix rate and engineer efficiency, respectively.

At the customer enablement level, the rate at which technical problems are resolved by customers without any on-site help increased by 76%, while also cutting travel costs for Xerox and minimizing downtime for customers. Customer satisfaction rates have risen to 95% as a result. [2]

End User (or Local Technician) Self-Service Empowerment

Reduce on-site service costs and problem resolution times by empowering customers to self-service with the right devices and solutions. Today's remote service solutions can be tailored to provide precise guidance to end-users.

A recent survey indicates this is more important now than ever, with 40% of end users now choosing to receive setup instructions on their mobile device and 71% preferring visual guidance self-installation methods. [3]

Together, optimizing service by increasing on-site technician efficiency and empowering customer self-service can lead to:

- Extending product service expertise and knowledge transfer across field service staff and customer base
- Empowering field operators to perform increasingly complex tasks, regardless of the experience level, through remote assistance enabled by XR
- Faster first-time fix rates and customer service outcomes

2 Harvard Business Review: Why Every Organization Needs an Augmented Reality Strategy, Nov 2017

3 Home Electronics Self Installation Survey Report - Complete Results (techsee.me)

These benefits are more than hypothetical—organizations are already seeing real, quantifiable results today.

From remote capabilities to enabling technicians and customers on site with XR-based solutions, service resolution can be delivered in several different modes. But like any strategic initiative, continuous improvement relies on data and insights. This brings us to our third and final question.

How might we measure and continuously improve service models with data-driven insights?

Advanced analytics blends inter-device connectivity and real time monitoring with predictive and prescriptive insights. These data-driven insights lead to improved decisions and preemptive service actions.

For example, if insights indicate that certain parts are frequently serviced or replaced, a company can take action to optimize warranty and product service costs. They may even prescribe design changes for the next version of the product.

Similarly, first-time fix rates and mean time to repair (MTTR) metrics can lead to better maintenance procedures. They also increase the understanding of specific technician skill levels and expertise for more targeted future training. User engagement metrics of the service application (XR or others) will also provide valuable insights on friction points related to user experiences, providing opportunities for continuous improvement of the service application as part of service optimization.

These insights are essential to continuously measure service model improvements and take a data-driven approach to continuously respond to evolving market expectations.

Practical steps to advance maturity from any starting point

Optimizing a service model is a multistep process that requires collaboration across a service organization and its related functions. Below are some actions to lay the foundation for step change, regardless of current maturity.

Understand current state relative to peers

Have you…

- Completed a diagnostic to assess internal capabilities spanning people, process, data and technology?
- Benchmarked against industry peers?
- Conducted a technical and organizational readiness assessment to advance to your next maturity stage (regardless of starting point)?
- Gathered baseline data and insights that will inform business case, roadmapping and future continuous value tracking efforts?

Develop and maintain comprehensive business case and roadmap

Have you…

- Taken your business case beyond a generic set of outcomes?
- Established key value realization and drivers aligned to the strategic imperatives of your organization? Included hard dollar, productivity, and intangible benefits in your value story?
- Developed user personas to tell the value story in a "day in the life" context?
- Maximized a path to value with a phased roadmap respective to your current state and value drivers?

Deliver continuous change campaign

Have you…

- Assessed stakeholders to identify potential influencers, resistors and influencers and to understand their respective motives and value drivers?
- Developed a platform of thinking that communicates and sells executives and stakeholders on the compelling reason for change?
- Formally established executive support, accountability, and expectations with a governance model?
- Established incentive structures for early adopters and evangelists?

Whether you are at the stage of adding smart sensors to your end user product / equipment or already reaping the benefits of predictive maintenance and an enterprise-wide library of XR experiences, these actions can help you plot your next step forward to a state-of-the-art service model.

As you tackle new service complexities and prepare for an increasing wave of smart connected products, now is the time to equip your organization with the tools and capabilities necessary to increase operational effectiveness and create strategic product differentiation.

The Future of Field Service: Three Use Cases for Smart Connected Operations

by Cris Bernabini and Johnny Bui

The COVID-19 pandemic continues to be devastating for many companies. Those that have survived have dramatically lost speed and efficiency as they made operational adjustments to adhere to new WHO guidelines.

Yet, among its devastating effects, COVID-19 also provided the ideal testing ground for digitally proficient enterprises to validate the effectiveness of the technologies they had been investing in.

This is the case for companies who were already driving transformation around the way they conduct field services. Most of the problem areas in field service pre-date the pandemic.

In this article, Kalypso examines three key opportunity areas around the field service experience.

These use cases cover a range of technologies, from easy-to-implement to more sophisticated, and they illustrate important ways companies can transform to respond effectively to customers' expectations in a post-pandemic world.

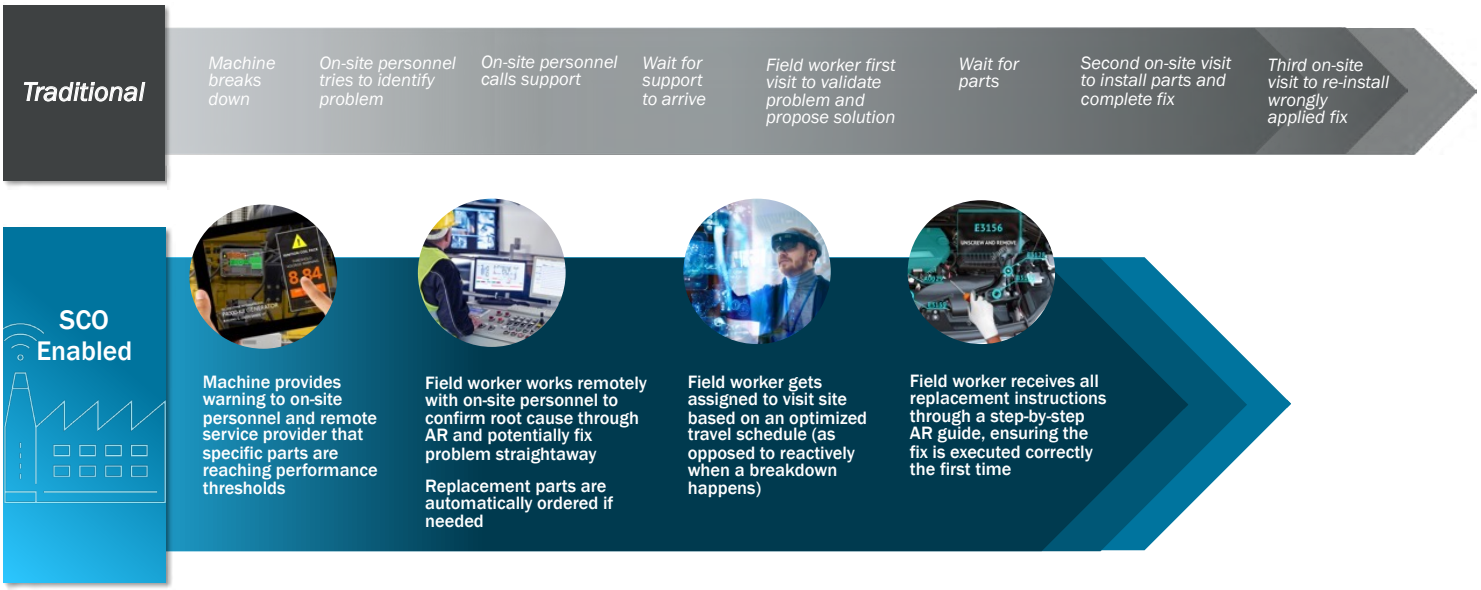
- Leverage digital technologies to enable remote access for field service
- Increase on-site staff efficiency with augmented reality (AR) work instructions
- Apply advanced analytics to optimize planning and scheduling of service activities

The Benefit of a Smart Connected Operations (SCO) Approach to Field Service

Before we jump into the use cases, it's important to level-set on the scope of the problem and how digitizing field service operations can help.

Traditionally, provisioning field service involves long lead times and costly site visits. As shown in the image below, after a machine breaks down the process includes identifying the issue, raising a support call, waiting for the engineer's visit and troubleshooting. In more complex cases, it also includes ordering spare parts and a second visit to perform the repair.

However, using a Smart Connected Operations (SCO)-enabled field service provision, the field service organization (FSO) can batch many of these steps into one, reducing the technician's onsite visit and ensuring that the technician is properly informed through every step of the way.



With a smart connected approach to operations, machines can warn personnel ahead of time when specific parts are likely to reach performance thresholds. This allows field workers to either work remotely with on-site personnel to service the machine or order replacement parts in advance for field service technicians to repair the machine.

In a SCO-enabled setting, the field service technician is assigned to the visit site on an optimized travel schedule, responding *preventatively* as opposed to *reactively.* Ideally, the technician would receive all replacement instructions through an augmented reality (AR) guide, shortening the turnaround time from machine failure to repair.

The following use cases will bring these ideas to life.

Use Case 1: Digital Technologies Enable Remote Access for Field Service

In the future, we can expect some ongoing requirements for socially distanced work, so field service companies have an opportunity to upgrade their offering to include smart-connected products (devices leveraging Internet of Things (IoT) connectivity) to better serve customers with industrial factory plants. For many companies, adhering to WHO guidelines keeps their workforce safe, but reduces productivity of business operations. This has given rise to the use of remote access solutions to manage and service devices without the need for site visits.

The benefits of a remote service model add up quickly. For example, one international manufacturer of integrated therapy systems had a network of 20,000 devices at 5,000 hospitals. Their shift to remote service has saved four to eight hours of travel time for each customer inquiry and a 50% reduction in mean time to repair (MTTR)

With 700 telephone consultations now resolved remotely per month, the cost savings really add up.

And remote access goes beyond reducing support costs. It also prolongs the longevity of the machinery and reduces downtime, maximizing the value of the machine.

Here's an example.

Rockwell Automation is a multi-national provider of industrial automation and software solutions. In March 2020, when a critical machine installation planned the previous year was just a few weeks away, it became clear that due to travel restrictions, Rockwell would not be able to send a team of field engineers to their customer. But without that new machine, the paper manufacturer's production would plummet, causing not just a revenue loss, but a shortage of essential products on the market.

Suddenly, going live with Live View Support – a service that Rockwell had planned to launch much later in the year – became urgent. Live View Support leverages augmented video calling during remote support calls. It is powered by PTC's Vuforia Chalk, which can be run on any handheld device.

Just ten days before the installation, the local field service engineer downloaded Vuforia Chalk and started testing the remote assistance technology.

The app allowed the customer to connect with experienced Rockwell technicians to share a live feed of the issues they encountered in the field. The customer could also to mark up the image, highlighting problem areas. Remote expert engineers were able to draw on-screen instructions for site workers to follow in real time, making the machine installation possible in under two days.

The paper manufacturer avoided a supply crisis, and the experience effectively proved that on-site assistance is not the only way to manage plant installation and service. Remote access delivered cost-effective resolution with a comparable lead time to a physical visit.

Another way companies can digitally enable remote access is software content management (SCM), which enables the creation of packages for immediate (or future) deployment of over-the-air updates. These packages can include software updates, security patches, audit logs, and file transfer.

As an example, one Kalypso client leveraging SCM is a major medical device manufacturer that partners with laboratories around the world. They have over 30,000 globally connected medical devices in the field. With SCM, they were quickly able to update their connected devices with new parameters to test for SARS-CoV-2 antibodies, over-the-air, without having to send a field service technician onsite.

Use Case 2: Augmented Reality-Assisted Work Instructions for On-Site Field Service

In addition to enabling fully remote service in the example above, AR can also provide support for on-site field service. For example, the Digital Assist Library is Rockwell Automation's cloud-based repository of augmented reality experiences, which was built to empower field workers to perform maintenance and repair procedures themselves.

Local maintenance technicians were finding the existing manuals cumbersome and struggling to find instructions to perform the tasks that were relevant to their specific case. There was also a real risk of misinterpreting the steps.

The Digital Assist Library leverages PTC's Vuforia View app to search for and display, on handheld and wearable devices, easy-to-follow step-by-step instructions for over 100 service procedures.

In a timed test run on the field, a service technician performing a maintenance procedure following the AR instructions completed it 62% faster than another technician reading instructions from the manual. Combined with the high user-friendliness of the app – which was rated 4.5 out of 5 for ease of use – the benefits case for AR work instructions is substantial. It also allows the customer to download the experience for offline use and to 'learn by doing' which delivers increased knowledge retention.

Use Case 3: Advanced Analytics and AI for Predictive Maintenance

As we saw above, connected products provide a host of benefits, including over-the-air updates and reduced site visits via remote assistance. Connected products also allow the application of advanced analytics on the data collected by these devices for predictive maintenance.

Another Kalypso client – a major supplier and distributor of natural gas compressors – needed a way to predict when their compressors would fail. Distributors of gas compressors deliver very large pieces of industrial equipment, which are typically spread out over very remote locations. For instance, one of the distributors we worked with traveled about 800,000 miles per month to service these compressor units.

First, we leveraged the distributor's data, gathered from their connected devices, to identify the typical maintenance cycle of a compressor. Then we used artificial intelligence (AI) to predict when a compressor is likely to fail, so that when the system detects an impending failure or critical status, it raises a notification to supervisors 30 minutes before the compressor breaks down. This predictive measure allows the distributor to perform a controlled shutdown.

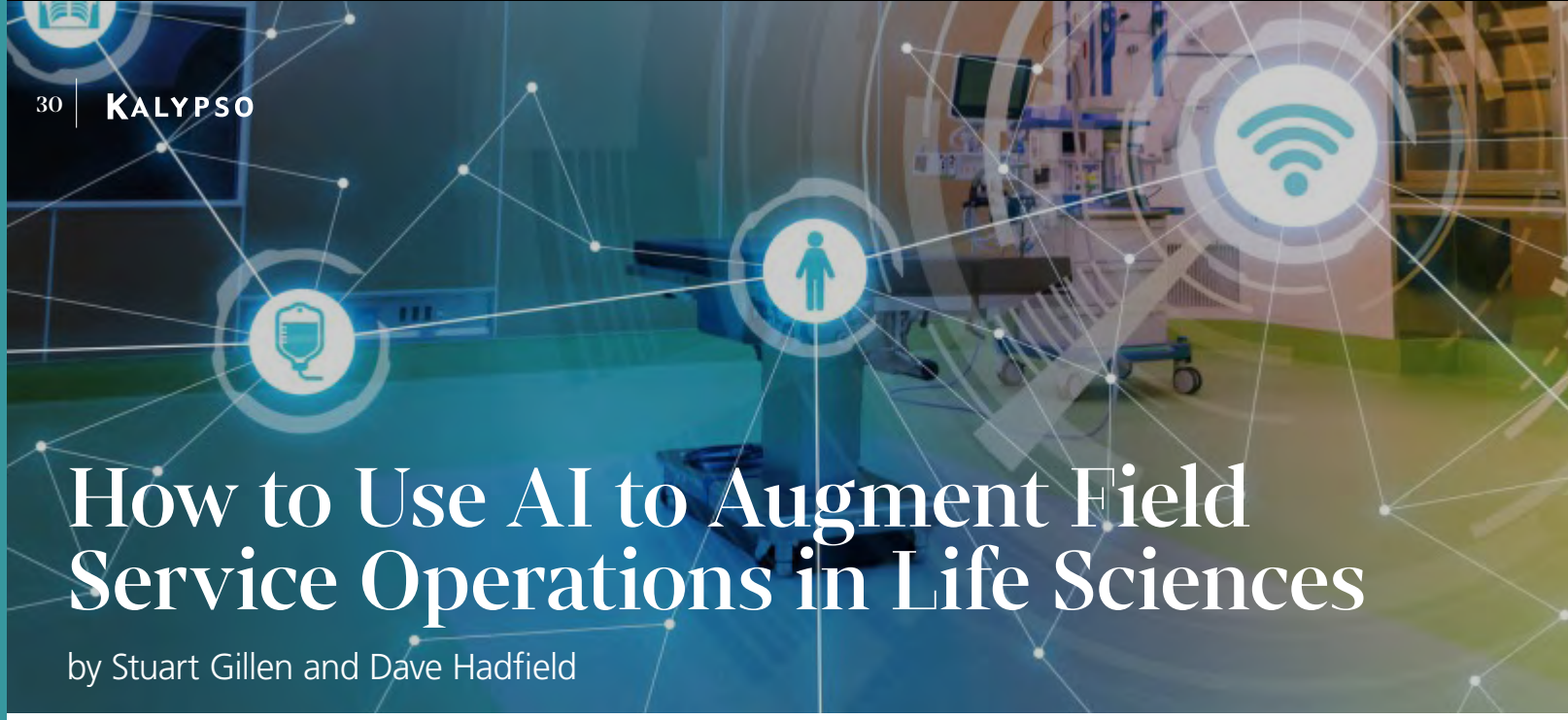
With Kalypso's help, the distributor was able to batch-plan their shutdowns and remote service calls, optimizing the amount of time that the operators and field technicians would have to spend in the field. We then developed AR applications for field service technicians to visualize information about the health of the machine and to access manuals and work instructions.

The beneficiaries of this service are not just the end users, but also the distributor's internal design/engineering team. These teams are now better prepared to track quality metrics and actual unit performance, when previously they had little understanding of how end users were using equipment. By understanding the true usage of compressors in the field, the design/engineering teams can optimize the design for longevity.

The Bottom Line

Every industry has been impacted by the COVID-19 pandemic, with varying degrees of severity based on their digital maturity prior to the pandemic. While some companies may have a stronger resilience to changing business operations, others will struggle to acclimatize themselves in the future. For field service companies, the difference will come in the form of smart connected operations.

The examples in this article illustrate how tangible, attainable benefits, such as reductions in MTTR and travel costs – as well as avoiding exposure to COVID-19 – are within reach of companies willing to digitally transform field service operations.



How to Use AI to Augment Field Service Operations in Life Sciences

by Stuart Gillen and Dave Hadfield

Even before the current crisis, life sciences companies were adopting artificial intelligence (AI) into daily service activities. As companies adjust to the reality of increased remote engagements, they can accelerate the trend towards connected field operations.

AI augments the service engineer, allowing him or her to make more informed decisions, better predict outcomes such as personnel scheduling and parts shortages, and identify and respond to product quality issues before they become critical for end users.

In a survey conducted in conjunction with Astea, Field Service Medical (FSM), and WBR Insights, the Internet of Things (IoT), AI, and preventative maintenance accounted for 63% of the top three items executives consider when purchasing a Field Service Management platform.

Here is how we see AI impacting day-to-day operations, both through and after the recovery.

Drive Out Complexity

It has been well documented that companies are losing skilled service personnel at a faster rate than they are backfilled, largely because baby boomers and Gen Xers are retiring, and millennials are not interested in field service work.

In a report by Manpower Group, 70% of the companies interviewed said they expected a skills shortage over the next 10 years. In addition to the loss of talent and knowledge, the sheer complexity of modern machinery makes it difficult for subject matter experts to keep abreast of best practices. Tools based on AI must be used to augment the SMEs' capabilities and bridge the skills gap.

The growing complexity of modern systems increases multi-mode failures which describe how many causes of failure act together to affect the performance of a system. With such complexity, it is almost impossible for one person to fully understand the intricacies of equipment operation, and historical service practices that used procedural lists and rules of thumb are ineffective in diagnosing root cause analysis.

I recently witnessed a hidden problem while helping diagnose a highly complex piece of equipment using AI. After the issue was resolved, root cause analysis identified two items:

1. The problem was severe enough that the organization wanted to ensure new models used in the field were fixed too. But as service engineers were deployed to fix the issue, they discovered the manufacturer of the equipment had already addressed the situation without updating them. Therefore, any rules which might have been developed to address this specific failure would already be obsolete on newer models.

2. Risk analysis indicated the severity was high, the mechanism for detection difficult, and the likelihood low (which is becoming the norm as machines become more complex). The sheer number of rules needed to catch these potential failures would require months of effort and become outdated with any new software and/or hardware revisions.

With AI, companies can quickly evaluate and visualize complex data sets to help uncover complex failure patterns never observed before. Artificial Intelligence augments the knowledge of highly skilled SMEs and guides them towards identification of multi-mode failures.

Significantly Improve Customer Satisfaction

For many companies, it used to take several hours to review service calls, support tickets and voice mails from angry customers to understand where the hottest fire was.

Today, connected devices provide enriched sensory information like operating hours, internal operating temperatures, fluids dispensed and diagnostic alarms. This means service organizations can apply AI algorithms to predict when a failure will occur.

Customer satisfaction ratings dramatically increase because technicians can provide guidance on impending breakdowns and organize maintenance around the customer's schedule.

In one example, a predictive maintenance package alerted the manufacturer to a tube failure of a CAT scanner seven days before it occurred, saving hospitals $100k/catch in replacement costs (not including labor and downtime costs). Moving from reactive to predictive maintenance can lead to 20-40% reduction in downtime and 15-30% reduction in maintenance costs. These AI-driven preventive maintenance alerts have a significant impact on reducing the cost of poor quality.

Optimize Spare Part Inventory (with a Flock of Seagulls?)

Spare parts management and optimization is important because it creates a more efficient process of identifying both availability and location of spare parts. Predictive maintenance algorithms identify when something is going to happen (to a specific model, in a specific region, with a specific failure mode), but before the technician gets in the truck, she is going to need to procure a specific part to fix the client's device.

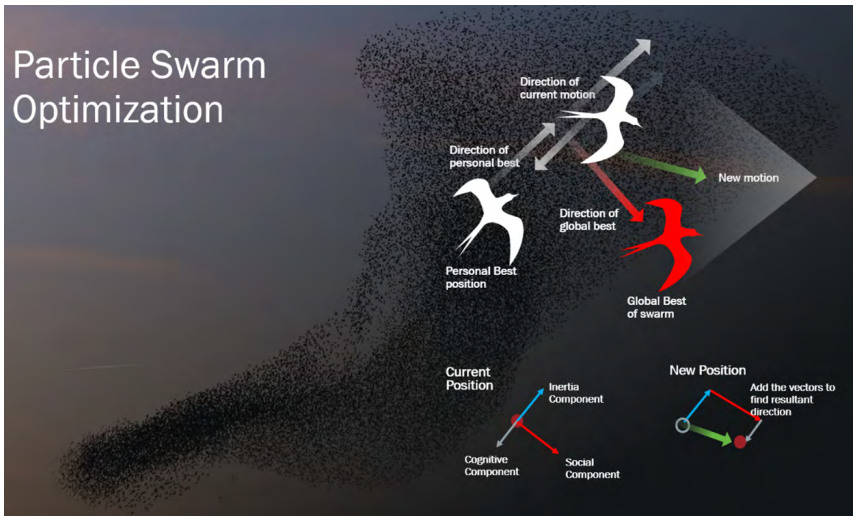
The question becomes: **Is that part on-hand?**

Although it might appear less expensive to simply buy and keep parts in stock, imagine the costs if the enterprise is running global operations. The costs to store parts in multiple field locations becomes expensive and the strategy quickly becomes impractical.

For the answer we can turn to nature and the majestic seagull. With advanced genetic algorithms and particle swarm optimization (PSO) techniques that mimic the behavior of flocks of birds, we can optimize the availability of stocked parts.

Imagine a swarm of birds, such as a flock of seagulls, seeking out their next meal. Many behavioral, social, and historical inputs exist which lead the group to finding the optimal solution given their current state.

If you consider a single seagull, it will try to seek food in one direction based on historical learnings and memory. But when you have the social component of the group, you capture the combined history of the flock, leading the swarm in the optimal direction. The flock gets to their dinner quicker than if all that existed was the information from a single individual.



These high-end optimization techniques can be applied to everyday service situations as well, seeking input from sources of field asset health data, cost data, service engineer availability, etc. By automatically executing millions of combinations and constraints, algorithms can generate optimal maintenance schedules along with part quantities that will minimize inventory carrying costs or enterprise impact costs. These AI-based optimizations ultimately allow companies to operate optimal predictive maintenance schedules with spare parts inventory, where the right parts are available in the correct quantities at the required locations.

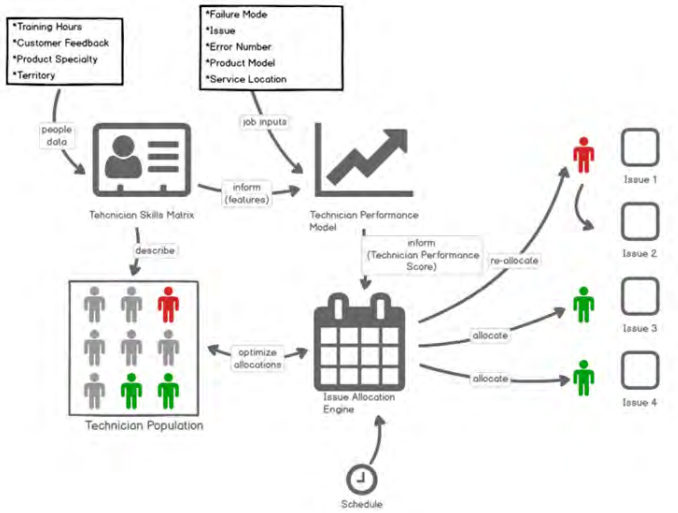
Achieve Efficiency via Intelligent Scheduling

Skilled personnel are retiring at a rate faster than positions can be filled. This forces organizations to maximize all available resources and overbook appointments to reduce overtime and unnecessary costs. With AI, organizations can put their most skilled people in the right locations at the right time.

This helps companies:

- Reduce travel times, fuel costs, and vehicle maintenance
- Ensure work orders and technician skillsets match, thus reducing the cost of lost appointments
- Avoid costly Service Level Agreement (SLA) penalties

Personnel scheduling has historically been a very manual, ad-hoc process that requires evaluating incoming jobs, allocating appropriate resources, and performing rudimentary sequencing and scheduling. There are several inputs in this equation including technician availability, the type of service required, device-specific training, and the expected service time per issue, which make scheduling a highly complex optimization problem for anyone.



And even once a schedule is defined, employees who are unwell, stuck in traffic, or delayed at other sites can cause them to start the process over again. There are too many variables for any single person to adjust all the levers, so an advanced analytics approach can help efficiently optimize the scope.

This image proposes a method where inputs from a digital skills matrix describe each technician in a workforce population. Skills including training hours performed, customer satisfaction metrics, product specialties, territory, etc., are used to build a technician performance model.

The model provides input to the Issue Allocation Engine which examines the entire population of technicians and work orders (using the Hungarian Algorithm for example) and optimizes the right set of resources based on the job inputs (failure mode of equipment, model type, service location, job duration).

With this type of optimization algorithm, we've seen our clients service organizations improve productivity from 10-20%.

Getting Started with an MVP Approach

There are clear benefits for companies that connect devices using AI and machine learning. But when it comes to getting started, there are a few key things to keep in mind.

The most important thing companies can do is consider current business challenges and apply an AI lens. When AI is used to help solve real, compelling business challenges, companies can realize real value quickly with a minimim viable product (MVP) approach.

The MVP approach is based on the idea that depth of value beats breadth of application. Instead of focusing on building a broad base of foundational AI capabilities generalized across multiple use cases, the MVP approach builds a full stack of capabilities and value focused on a narrow, high-priority use case.

This full stack starts with foundational connectivity and data models, and also includes descriptive analytics, root cause analysis, predictive modeling, and all the way up to prescriptive modeling and optimization.

When value is realized for the high-priority use case (ideally linked to a significant business challenge), companies can then scale for additional use cases.

Successful service companies are thinking about AI now. Part of adapting to the new normal will be adapting strategies to put remote work first. This might come from an MVP around predictive maintenance of failures, which would allow technicians to be onsite for only the most critical of issues. It may come from improved technicain scheduling, minimizing windshield time while maintaining or exceeding customer satisfaction metrics during this challenging time.

AI doesn't have to be a mystery. Avoid black box approaches based on proprietary, 'behind the scenes' data sets and analysis. Instead, provide business context and a strong value case, and apply an agile MVP approach. You'll enable platforms and methodologies that will sustain ROI for years to come.

Unlock Innovation with Smart Connected MedTech

Leveraging the power of IoMT expands opportunities for new functionality, far greater reliability, much higher product utilization, and capabilities that cut across and transcend traditional medical device product boundaries.

Companies are driving value through:

- **Reimagining** how value is created and captured through new medical technology use cases, value chains and business models
- **Engineering** "smart" components such as sensors, microprocessors, data storage, software, embedded operating systems and enhanced user interfaces
- **Connecting** disparate devices and applications to enable access to multiple data sources
- **Building** complete IoMT solutions and Augmented Reality (A/R) experiences quickly and easily
- **Analyzing** complex device data for real-time insights, predictions and recommendations
- **Experiencing** and engaging with devices in a more contextualized, actionable way
- **Managing** the performance of smart connected devices, processes and systems
- **Servicing** equipment remotely, speeding up resolution time and eliminating the costly field service technician visits
- **Accelerating** time-to-value and return on investment (ROI) of IoMT initiatives

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Wherever you are in your Smart Connected MedTech journey, Kalypso can help you define a strategic roadmap, develop a business case, build new offerings and/or enhance existing capabilities to quickly capture business value.

We have deep experience combining product value chain expertise with digital technology to drive transformation and enable value-based healthcare. We work across the full healthcare ecosystem including provider groups, medical device suppliers, pharma/ biotech companies and payers, bringing unique insights and extensive domain expertise to our clients.

Ready to Get Started?

Let's advance your Connected MedTech capabilities. Contact us today.

Rodney Holmes
Senior Manager
rodney.holmes@kalypso.com

Analilia Morales
Lead Designer
analilia.morales@kalypso.com

Dave Hadfield
Director
dave.hadfield@kalypso.com

Daniela Gallegos
Senior Designer
daniela.gallegos@kalypso.com

Venkat Gopikanth
Senior Manager
venkat.gopikanth@kalypso.com

David Comerford
Senior Consultant
david.comerford@kalypso.com

Learn more

kalypso.com