THE DIGITAL TRANSFORMATION OF MEDICAL OEMS

Enabling Digital Transformation with Industrial IoT:
For Medical Device Original Equipment Manufacturers

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Contents

Introduction ......................................................... 03
Medical OEMs Today ................................................. 04
Industrial IoT as a Solution for OEMs ................................ 07
Getting Started with Your IIoT Implementation Strategy ............... 11
Selecting the Most Appropriate IIoT Solutions ........................ 12
How MachineMetrics Can Help Medical Device OEMs ..................... 14
Conclusion ............................................................. 15
Introduction

NEW CHALLENGES

Increasing costs, non-commoditized products, and strict compliance policies are just three of the major challenges medical device manufacturers currently face. To meet these challenges, medical device manufacturers have traditionally adopted lean manufacturing practices. However, to confront the rising competition, medical device OEMs and manufacturers are now turning toward Industry 4.0 solutions.

The growing concept of digital transformation provides a greenfield opportunity for manufacturers to solve ever-growing challenges in the industry. This includes optimizing manufacturing processes using machine data, leveraging real-time analytics, and remotely monitoring machines, all of which can contribute to large increases in productivity. To help medical device manufacturers stay compliant, as well as grow production and increase revenue, a top-down approach is required. This starts with the original equipment manufacturers (OEMs) producing the factory equipment medical device manufacturers use and then moves on to the manufacturers themselves and the end-users of the medical devices.

This approach eliminates the challenges medical device manufacturers face when it comes to maximizing shop floor operations, and ensures accountability starts with OEMs. In a world defined by value-driven healthcare and accountability, OEMs must now design and develop equipment that supports new business models for medical device manufacturers.

The Industrial IoT (IIoT) and the digital transformation it enables, provide OEMs producing medical device manufacturing equipment with a means to reinvent and optimize the machines for its niche market.
In an industry that relies on collaboration to ensure accountability, the demands of both medical device manufacturers and OEMs are sometimes intertwined. For the OEMs, the possible scenarios when developing shop floor equipment include:

• The need to offer value-based equipment to medical device manufacturing enterprises
• Designing innovative equipment that meets the evolving technological, security, and operational requirements of medical device manufacturers
• Protecting and growing the profit margins on niche equipment that elude commoditization.

For medical device manufacturers, some specific challenges require support or solutions from the OEMs producing the equipment used on factory shop floors. OEMs must also address these possible roadblocks, which include:

• The increasing cost of equipment used in manufacturing medical devices
• The government regulations and policies that must be adhered to, ensuring accountability
• The ability to track machine utilization and the need for remote machine monitoring to optimize productivity.

INCREASING COSTS AND THE NEED FOR VALUE BASED EQUIPMENT

The cost of shop floor equipment is constantly on the rise due to the life-cycle expenses associated with this equipment. These include maintenance and repair, installation, and operator training.
In every scenario, medical device manufacturers are expected to bear these monetary outlays which, in turn, lead to increases in the cost of the end product.

OEMs can reduce the financial burden on medical device manufacturers by developing machines and services that offer more value for every piece of equipment purchased. The butterfly effect that comes with providing value-based equipment includes reduced costs in manufacturing, increased equipment life cycle, and reduced costs of medical devices to the public.

**DESIGNING INNOVATIVE EQUIPMENT TO OPTIMIZE PRODUCTION**

The adoption of Industry 4.0 initiatives in the medical device manufacturing industry means OEMs must design equipment that fit into smart or digitized facilities. Accomplishing this begins with understanding how medical device manufacturers make use of the equipment they purchase.

Innovating for the medical device manufacturer starts with understanding shop floor dynamics, the need for interoperability among shop floor assets, and ensuring ease of use. Knowledge of shop floor dynamics is generally driven by data capture and analytics. This information will help OEMs highlight both the known and relatively unknown challenges medical device manufacturers face with machine utilization.

**MEASURING MACHINE UTILIZATION AND ENABLING REMOTE MONITORING CAPABILITIES**

Optimizing shop floor processes and developing innovative equipment starts with measuring or capturing important machine and operational metrics. Although knowledge of machine utilization provides medical device makers with the insight needed to maximize manufacturing processes, it also enables OEMs to provide answers to some challenges.

One example is upgrading legacy machinery or the development of newer versions of available equipment to meet the technological requirements of Industry 4.0.
The annual service cost associated with technicians making repairs or undertaking maintenance is estimated at $50 billion. This figure doesn’t take into consideration the cost of purchasing replacement parts, therefore highlighting how expensive maintenance is for medical device manufacturers.

One solution is remote machine monitoring. This provides multiple ways to reduce the financial burden of outsourcing maintenance, which can reduce the purchasing and operational capabilities of medical device manufacturers.

**GOVERNMENT POLICIES AND REGULATIONS**

Due to the sensitive nature of products on offer, the medical device manufacturing industry is one of the more regulated industries. For example, in the United States, the Food and Drug Agency (FDA) released a Compliance Policy Guide to ensure manufacturers integrate safety measures when producing devices.

For OEMs manufacturing these devices, guidelines — such as the need to provide recommended maintenance schedules to keep equipment in compliance with every applicable performance standard — must be adhered to.

Taking the US State of Illinois as an example, OEMs are expected to provide manufacturers with the advanced diagnostics and repair information they need to use their equipment at a fair price. Missouri takes this policy further, including the provision of repair tools to manufacturers using this equipment.

Supplying the predictive maintenance recommendations and documentation the government expects can be challenging to OEMs who don’t monitor machine use. Providing these added value-based services at a reasonable cost can also affect the profit margins of OEMs when poorly handled.
Industrial IoT as a Solution for OEMs

The Internet of Things brings a measure of benefits to manufacturing operations that, when applied, provide a pathway to solving the dilemmas OEMs face when developing equipment for medical device manufacturers. The applicable IIoT solutions refer to IoT hardware or devices, IoT software applications, and IIoT platforms. With IIoT, OEMs can build digital transformation strategies that:

- Monitor equipment performance for developing proactive maintenance policies and improving product quality and capabilities
- Aggregate and analyze data to help medical device manufacturers optimize machine utilization
- Deliver or integrate actionable insight into factory operations and workflows
- Integrate both available and upgraded industry standards into workflows and produced equipment
- Enable the creation of new revenue streams to support small or declining profit margins
CONDITION MONITORING ON THE SHOP FLOOR

The process of condition monitoring involves collecting the relevant data on the shop floor, aggregating and analyzing it to understand specific phenomena, and identifying significant changes or effects on machine or shop floor operations.

To effectively capture data, a comprehensive digital transformation of the shop floor is required. IIoT provides the best tools required to manage this transformation for OEMs producing medical device manufacturing equipment.

Within the average shop floor, conventional machines with legacy communication systems operate alongside more modern equipment. The installation of IIoT hardware such as sensors or human-machine interface devices on legacy equipment enables data capture and connectivity with other machines in the vicinity.

IoT platforms then provide a centralized storage and computing location for storing and processing the data captured from both legacy equipment and the larger connected system. Analyzing the captured data then provides answers to condition monitoring questions.

For example, you could diagnose the cause of downtime or execute overall equipment effectiveness calculations for individual machines (or the entire shop floor) to optimize the manufacturing process.

Shop floor data also provides the actionable intelligence needed to develop predictive and proactive maintenance schedules to ensure unplanned downtime is drastically reduced.

INTEGRATE GOVERNMENT REGULATIONS AND INDUSTRY STANDARDS

Effective quality management and compliance policies rely on the ability to continuously monitor every aspect of a production cycle. These can include equipment calibration and recalibration, time-sensitive automated activities, scheduled workflows, and granular data like equipment temperature or vibration. Let’s take the automated industrial lathe machine used to rotate work pieces as an example.
Quality controls and standards exist on the desired symmetry when cutting materials along an axis. To ensure quality is consistent when mass producing equipment, specified cutting standards with respect to cutting tool vibrations must be adhered to. In other situations, the ambient temperature and other environmental factors can also lead to quality variations.

The data capturing abilities of IoT ensure important machine and production parameters such as temperature, vibration, and cutting symmetry can be monitored and analyzed to better understand the effects of slight variations on product quality.

IoT hardware is used to capture specific data or control environmental components such as HVAC systems while IoT platforms provide the computing resources and tools to handle complex analytics in respect to quality control.

**AGGREGATE AND ANALYZE MACHINE DATA**

Analyzing medical device manufacturers’ machine data provides a solid foundation for optimizing the design and development of innovative equipment, as well as helping to provide OEMs with efficient after-sales services to the end-user.

IoT platforms provide a scalable and flexible ecosystem for capturing machine data from a wide array of equipment deployed on the shop floors of medical device manufacturing facilities. For example, a cloud-based IoT platform has an infinite storage capacity which OEMs can deploy to capture specific machine data from all the equipment they have deployed.

The collected data can then be used to analyze the average performance of the medical device manufacturing equipment across shop floors with diverse settings and operations. The information gained from analyzing end-user machine data across Med-tech facilities provides the actionable insight needed to produce equipment that comes with all the add-ons specific government agencies require.

Monitoring and analyzing end-user machine data also creates avenues to generate profit while providing more value-based services to medical device manufacturers. The application of IoT ensures monitoring a vast array of machines can be affordably achieved through the integration of IoT hardware into machines with permission from medical device manufacturers.
The analyzed data can then be leveraged to provide after-sales maintenance services and optimized usability packages at affordable subscription rates to generate revenue.

**ENABLE REMOTE MACHINE MONITORING**

The smart factory of the future is one that functions with minimal direct input from human operators. For OEMs producing medical device manufacturing equipment, embracing the automation defined by Industry 4.0 requires the ability to monitor machines remotely.

Today, IoT, in conjunction with Edge computing, provides the best solution for remotely monitoring machines and processes across both small and large-scale manufacturing facilities.

The ability to remotely monitor interconnected shop floor machines means an OEM can visualize shop floor operations from the perspective of either a single piece of equipment or that of the entire manufacturing operation. The insight gleaned from remote machine monitoring can be leveraged to reduce machine downtime, develop maintenance schedules and optimize production cycles to increase throughput.

IoT-enabled remote monitoring also provides OEMs with an avenue to simplify the repairs and maintenance services offered to the medical device manufacturers using its equipment. Integrating IoT or Edge devices into machines or on shop floors ensures collected data can be streamed to an IoT platform which the OEM’s technician can access.

The technician can then analyze the streamed data from any location to troubleshoot the equipment issues without having to physically visit the medical device manufacturer’s facility. The remote machine monitoring service reduces the expenditure on repairs for medical device manufacturers and ensures the OEM’s technicians are engaged with on-premise activities.

The MachineMetrics Edge easily connects machines to the MachineMetrics cloud service using Wi-Fi, cellular connectivity, or an ethernet connection.
Proper implementation is required to successfully deploy IIoT as a solution to the challenges faced by OEMs producing equipment for medical device manufacturers. Statistics show that without proper implementation procedures, IIoT deployments are more likely to fail than succeed. This high failure rate is due to the challenges OEMs encounter.

These challenges include:

- Issues with interoperability and data management
- The costs of deployment, the deployment process, and the learning curve associated with receiving insight from data analytics
- Issues related to connecting IoT hardware and software technology, plus existing equipment.

In terms of issues with deploying IoT solutions and ensuring interoperability, OEMs sometimes struggle to install IoT solutions across shop floors.

In facilities with legacy equipment, the difficulties with deploying IoT solutions increase as this equipment sometimes lacks the features needed to capture, transfer, and receive data from an IoT network.

OEMs who intend to build IoT platforms from scratch also struggle with the associated costs required to do this. Research shows that 76% of DIY IoT implementations fail because most enterprises do not have the technical know-how to build IoT platforms from scratch.

Thus, to ensure a successful implementation, OEMs must develop actionable IIoT strategies that provide solutions to specific challenges.

The starting point to a successful strategy is determining what you intend to achieve with an IIoT deployment and understanding which IIoT solutions and features best suit your facility. This should include hardware and a supportive IoT platform—the most important step towards a successful implementation.
Selecting the Right IIoT Solution

SELECTING THE MOST APPROPRIATE IIoT SOLUTIONS FOR YOUR MEDICAL DEVICE EQUIPMENT MANUFACTURING FACILITY

If you have decided to pursue a digital transformation initiative using IIoT with the aim of improving production quality, providing better after-sales services, regulated condition monitoring, and generating more revenue, then this checklist for choosing a solution will help inform your purchasing decision.

1. **Available Connectivity Options**
   When shopping for an IoT platform, analyzing the options it provides for connecting your equipment to the internet to transfer data is an important consideration. IoT hardware can also be used to bridge the connectivity gap for legacy equipment. Consider the hardware options and communication protocols that ease connectivity issues, not hinder them.

2. **Scalability Support**
   An increasing customer base, facility capacity expansions or increased integration of IoT devices require more storage and computing resources for proper management. A best-in-class IoT platform must be agile enough to accommodate your changing business needs.

3. **Class of IoT Platform**
   There are varying types of IIoT platforms, and they are differentiated by the features they offer and their usage. Some vendors offer IoT platforms purely dedicated to data storage, device management, or process management. Industrial-grade IoT platforms provide end-to-end solutions for diverse applications, are flexible, and cater to your changing needs. They provide support for basic tasks like data storage plus complex activities such as developing a custom IoT application.

4. **Custom Integrations and API Access**
   OEMs who intend to deploy IoT to capture data from purchased equipment must consider the ability of an IoT platform to integrate with and communicate with either proprietary or non-proprietary applications or devices. Vendor solutions that don’t support integration and API Access limit the ability to integrate with other IoT or cloud services.
5. **Ease of Use for Data Capture, Management, and Analysis**
How the IoT solution facilitates the capture of data from the shop floor and their deployment processes are important considerations. The available off-the-shelf features and applications for managing, analyzing and visualizing data must also be considered. We recommend a plug and play solution where IoT hardware is easily installed and equipment is intuitively connected.

6. **Security and Privacy**
OEMs who intend to collect data from the equipment they sell to medical device manufacturers must consider the security challenges that come with using IoT to capture data. That means carefully evaluating the security measures a vendor puts in place to protect equipment data.

7. **Pricing Models**
The integration of IoT by medical device equipment OEMs is expected to solve challenges such as increasing low-profit margins and providing avenues for revenue growth, rather than draining available resources. Compare the pricing models a vendor offers and evaluate the options for up-scaling or down-scaling according to your requirements.

8. **After-service Support**
Large-scale IoT ecosystems are complex and challenges with implementation and integration with existing systems may occur. In these situations, select a reliable vendor that provides you with all the support you need when challenges come up.

9. **Industry-specific Experience**
The data analytics requirements for OEMs producing medical device equipment is specific to the industry. IoT solutions or IoT platforms must be capable of servicing the specific needs that come with your unique manufacturing processes. Your search must consider IIoT vendors that offer IoT applications built specifically for the medical device equipment manufacturing industry.

10. **Update Consistency**
The process of updating the IoT applications you use has the capacity to cause unplanned downtime because of service disruptions. In situations where you are tasked with handling updates, the complex nature of the process could prove challenging to a non-technical person. A seamless upgrade policy and process should be the preferred option when choosing an IoT solution.
How MachineMetrics Can Help Medical Device OEMs

The MachineMetrics’ Performance Dashboard is an easy to use, intuitive interface that gives factory workers the information they need to make faster, more confident decisions.

The MachineMetrics suite of IoT solutions provides the industrial-grade hardware and a cloud-based IoT platform to help OEMs manufacturing equipment for the medical device industry to achieve their digital transformation goals.

These solutions — which includes the MachineMetrics IoT hardware and IoT Platform — guarantee ease of use through self-installation and the customer support MachineMetrics provides.
The MachineMetrics IoT Platform provides your facilities with the following features for implementing digital transformation strategies:

**Plug and Play Installation Process**
The MachineMetrics IoT Platform supports the connection of legacy equipment with analog I/O, as well as modern equipment. This makes connecting equipment on the shop floor to the platform a seamless process. The ease of installation simplifies the task of building an IoT network to capture data from the shop floor.

**Automated Data Aggregation and Processing**
MachineMetrics employs the use of an automated data transformation engine to aggregate machine data in real-time. Automating the aggregation process means as data is captured, the engine immediately categorizes the data according to specified rules or use cases. This allows OEMs to capture large data sets from the diverse equipment purchased by medical device manufacturers, regardless of where the equipment is located. The data sets are instantly analyzed to recognize patterns, highlighting machine utilization. The equipment manufacturer can then use the aggregated data to develop optimized equipment, create predictive maintenance schedules, or provide remote maintenance and repair services.

**Open Integration and Application Development Support**
MachineMetrics supports open IoT implementation and communication protocols such as OPC Unified Architecture and MTConnect, as well as proprietary IoT implementation solutions. The API access MachineMetrics provides makes it possible for OEMs to integrate third-party applications or software within its IoT platform. OEMs can also choose to develop customized data analytics applications and deploy them on the MachineMetrics platform to analyze captured data.

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**Conclusion**

The application of Industrial IoT provides medical device OEMs with a pathway to digital transformation while pursuing Industry 4.0 business models.

The deployment of IIoT gives manufacturers the ability to capture data from original equipment across both small and large-scale manufacturing facilities around the world.

Capturing data provides the basics for innovation when building medical device manufacturing equipment and devising ways to offer value-based service alongside equipment to the medical device manufacturing industry.
ABOUT MACHINEMETRICS
MachineMetrics is accelerating digital factory transformations by providing an intuitive and flexible industrial IoT platform to easily collect and transform data from any piece of manufacturing equipment into powerful, actionable applications.

Right now, hundreds of manufacturers have connected thousands of machines to MachineMetrics across global factories to reduce machine downtime, optimize capacity, and drive increased throughput and profitability for their manufacturing operations.

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