A CASE STUDY PRESENTED BY AXENDIA

# SYSMEX LEVERAGES THE INTERNET OF MEDICAL THINGS (IoMT) TO DISRUPT THE BLOOD TESTING MARKET

# INTRODUCTION

## Sysmex Leverages ThingWorx to Improve Health Care for Millions of Patients by Doing More Than Just "Building a Better Box"

Today, the goal of healthcare is improving diagnostics and patient outcomes. To this end, the healthcare ecosystem is undergoing a transformation aimed at improving the quality of care while simultaneously controlling costs. In simple terms, the model is shifting from sick-care to well-care.

Innovations in medical practice, products and the Internet of Medical Things (IoMT) are enabling smart connections between technology, people, processes and data that support patient centered healthcare and drive improved diagnostics and patient outcomes in a cost effective manner.

### The power of the IoMT and advanced technologies are enabling businesses to think outside the box.

In the case of Sysmex, the company went beyond just building a better box in support of improved patient outcomes.

Sysmex is the leading developer of best-in-class, in vitro diagnostic hematology and clinical laboratory products in more than 190 countries. In fact, Forbes has recognized Sysmex among the World's Most Innovative Companies.[1]

At Sysmex, innovation is in the blood.

### "The continuous innovation in our products, testing and quality processes, and in how we partner with our customers, have powered improvements in health care for millions of patients,"

said Ralph Taylor, chief executive officer. "Our employees are the most innovative part of Sysmex, and their ingenuity and passion for creating unique and innovative value make it possible for us to shape the future of healthcare."

Sysmex has earned high Customer Satisfaction Ratings for the past 11 years for "Overall Service Performance" as a result of "innovation" in service & support.[2]

In November 2017, Sysmex reached an innovation milestone when the FDA cleared Sysmex's XW-100, a Clinical Laboratory Improvement Amendments (CLIA)-waived, first of its kind CBC (Complete Blood Count) analyzer developed specifically for the point-of-care environment. The XW-100 allows patients to receive diagnostic results for common blood tests in as little as three minutes in a healthcare provider's facility as compared to days from non-clinical settings.

This innovation was made possible by the Internet of Medical Things and ThingWorx, a leading platform for IoT innovation.

[1] forbes.com/companies/sysmex/
[2] IMV ServiceTrak 2017 Hemotology

# SHIFTING FROM SICK-CARE TO VALUE-BASED CARE

Historically, healthcare has been episodic and reactive — primarily aimed at addressing a malady, illness or injury after it has already happened. As a result, traditional healthcare models could better be described as "sick-care." This sick-care approach is backwards, expensive and unsustainable.

Sysmex is supporting the shift to value-based care models and improving patient outcomes by enabling same-day doctor-patient result review, during the same visit by identifying issues before they become critical.

## ...while laboratory tests represent just two percent of health care spending, they influence 70% of medical decisions.

According to the Health Industry Distributors Association, while laboratory tests represent just two percent of health care spending, they influence 70% of medical decisions[3]. Healthcare providers rely on a variety of methods to determine whether infections are caused by bacteria or a virus; CBC tests are among the first screenings in the process. Only 32%[4] of primary care facilities offer on-site testing, while others send blood work to outside laboratories and await the results. With a renewed focused on patient outcomes, timely intervention can support the shift to value-based care. Historically, providers file claims based on a fee-for-service: the type of test that was ordered, the type of diagnostic procedure, or even the type of surgery that was performed. However, in the outcome economy claims are filed based on the outcome of the test or procedure to the benefit of the patient.

According to the FDA, "A CBC is one of the most common physician-ordered tests used to evaluate a patient's blood levels, determine if an infection is present and if immediate intervention is needed. However, in the current health care setting, non-hospitalized patients who require a CBC can experience at least a 24-hour wait for test results, if not longer, when the test is performed by an off-site laboratory[5]," said Donald St. Pierre, acting director of the Office of In Vitro Diagnostics and Radiological Health in FDA's Center for Devices and Radiological Health." This waiting period may be detrimental to the health of patients whose care depends on quick results to rule out conditions that may require immediate medical intervention. With the device cleared today, processing time may now be reduced by making testing available in these additional settings."

## The Sysmex XW-100 supports improved outcomes by enabling faster decision making and operational efficiency for health care practices.

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[3, 4] hida.org, Impact-of-Diagnostics-on-Healthcare-Outcomes.pdf
[5] fda.gov, Press Announcements

# USING IoMT TO DISRUPT THE BLOOD TESTING MARKET

IoMT is fostering connections among a variety of devices including biometric sensors on personal wearable devices. IoMT connected devices are playing an increasingly important role in supporting improved diagnosis, quality of care, patient outcomes and improving the business of healthcare in the outcome economy. It is enabling the transition to patient centered preventive care.

In 2005, Sysmex began its IoMT journey with the support of PTC's ThingWorx platform by implementing basic communication capabilities to field instruments for remote monitoring. Adopting a value-added IoMT strategy allowed the company to provide a remote service offering to approximately 66 percent of its total customer base, resulting in maximized instrument uptime and service efficiency.

As an industry leader driven by innovation, Sysmex realized that it needed to do more than just 'build a better box.' In a recent interview[6], Andy Hay, Chief Operating Officer at Sysmex America stated, "There are some very big gaps between where the laboratory industry is as a whole and where we need to be to survive in the post PAMA-era..." referring to the 2014 Protecting Access to Medicare Act, which will cut an estimated $670 million per year from Medicare lab reimbursement beginning this year." He added,

**"It is no longer going to be sufficient to sell instruments. You've got to put a wrapper around them that demonstrates their value to the patient experience."**

Using IoMT technology on blood analyzers, service engineers can identify issues, perform calibrations, and predict several potential causes for short-term failure without even touching the analyzer.

The use of IoMT also enables Sysmex field staff to provide customers advanced tools to help them achieve their own operational efficiencies.

## Improving device availability through IoMT increases service readiness and ensures consistent instrument performance in the field resulting in improved patient outcomes.

As a result of the XW-100's clearance for use at the point of care, Sysmex will be able to increase the addressable market for this device from hundreds of sites to tens of thousands of healthcare facilities and non-traditional laboratory sites, including physicians' offices, clinics or other types of health care facilities with a CLIA Certificate of Waiver around the globe. The "CLIA Waived" status enables operators with no specialized skills to safely perform test procedures.

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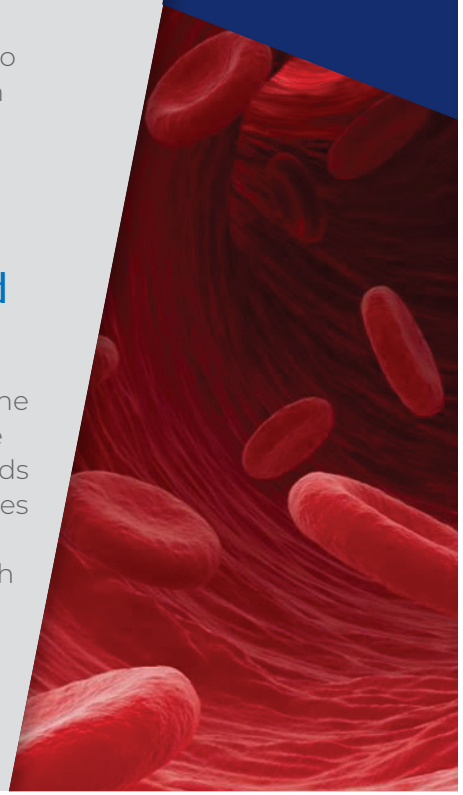

[6] captodayonline.com

# IoMT RAISES SHIELDS TO SAFEGUARD PATIENT SAFETY

To achieve CLIA clearance, Sysmex created a digital safety shield using intuitive connectivity with ThingWorx. Sysmex uses IoMT connectivity to engineer protective shields to safeguard/protect patient safety. The instrument communicates via PTC's ThingWorx to the Sysmex hematology management system database to verify that expiration dates and lot numbers for Quality Control (QC) materials and reagents are valid as well as the acceptable QC assay parameter ranges. The analyzer is designed to require QC material to be used every 8 hours. The instrument is also able to 'phone home' and verify if it is authorized for use. Furthermore, the instrument is self-checking and self-verifying to prevent the equipment from running if it is not properly set up.

In addition, the analyzer provides simple instructions for operator actions when results are flagged or outside of a specified range. To further ensure accurate testing in this setting and to eliminate results that are most susceptible to inaccuracy or require additional testing, the number of hematology parameters has been reduced.

**By using this digital safety shield, Sysmex demonstrated to the FDA the test's ease of use and low risk of false results when used by inexperienced operators.**

To verify this claim, the FDA reviewed data from a study conducted on 582 samples collected from patients ranging from 2 to 92 years old. The study compared the XW-100 test results collected by non-medical personnel in CLIA-waived settings to a hematology analyzer in an accredited clinical laboratory. The study results showed that by following the manufacturer's instructions for use, accurate testing can be effectively conducted by less skilled personnel.

The XW-100 was designed from the ground up for use at the point of patient interaction without the support of highly skilled technical lab staff.

**The embedded logic, supported by its IoMT connectivity ensure only safe results will be available.**

For complex clinical situations, the physicians are prompted to send the sample or the patient to a hospital or other CLIA moderately complex testing lab, for a more comprehensive testing procedure.

The XW-100 was designed from the ground up for use at the point of patient interaction without the support of highly skilled technical lab staff.

# GOING BEYOND BUILDING A BETTER BOX

"The nature of IoMT enables data driven actions in real-time," said Steve Postma, Enterprise Architect and Innovation Leader at Sysmex America.

## "To provide our customers a total system solution, Sysmex deeply integrates IoMT into the product 'and' into the business processes using real-time data to find 'evidence' of the need for intervention.

IoMT enables us to improve medical device reliability, monitor medical measurement precision and accuracy via quality control processes or perhaps operator information and training. Evidence via data and analysis tools are the foundation of targeted actions comprising a total system solution," he added.

Sysmex views IoMT as a strategic initiative as the paradigm shift of service models in the diagnostic industry requires innovative companies to delink a fast growing install base from support staff and instead ensure high availability of instruments. From a maintenance and reliability perspective, it enables the company to focus on equipment uptime and availability.

To support its availability goals, Sysmex uses Servigistics, PTC's industry-leading service parts optimization solution, which analyzes dozens of variables to predict part failures. Referencing those forecasts, Servigistics finds the most cost-effective inventory management strategy to ensure Sysmex's service teams have the right parts, at the right place, at the right time, thus eliminating unplanned parts-related downtime.

## For Sysmex, the four corner stones of "going beyond a better box" are:

### Next Generation Diagnostics
Greater accuracy, specificity, productivity

### Advanced Tools and Technologies
Superior insight and control, enhancing speed to treatment

### Process Optimization
Automatically balances work-flow and routine tasks

### Harmonized Support
Driving improvement, supporting your staff, helping you plan for the future

Sysmex is also moving forward with deploying ThingWorx Analytics, powered by IoMT into Clinical Trials and Evaluations with customers, as well as examining its potential within the design and sustaining engineering of its products. "The value of the PTC and Sysmex relationship is visible to our global colleagues. Projects such as Beyond Care Quality Monitor (BCQM) and Evidence-Based Maintenance (EBM) have been discussed at global executive forums and Sysmex Corporation of Japan has great visibility to our successes that come from our relationship with PTC," said Hay. He added, "Sysmex America's innovation team continue to push forward the boundaries of applying the ThingWorx platform to our instruments and our processes.

## We are piloting Digital Twin using AR and IoMT and are developing use cases for AR within staff and customer training, for example."

The company will also be embedding technology in all future design. All aspects of US driven innovation are being fed back into R&D in Japan to become standard in future instrument designs.

"The XW-100 is a breakthrough that will transform blood testing for patients and the health care professionals who treat them," said Ralph Taylor, chief executive officer of Sysmex America."
In addition to making faster treatment plans possible, the technology will improve the efficiency of healthcare delivery. Sysmex has developed and implemented a model for expanding access to care and reducing the cost of care through an IoMT-connected medical device.

## Benefits of going beyond the better box and increasing value for its customers with the XW-100 include:

### Faster results
to alleviate patient concern regarding the cause of their symptoms

### Earlier start
of treatment plans

### Avoiding the need to travel
to more than one location and follow-up visits to a doctor's office to discuss test results

### Lock out of patient testing
if quality control results are out of range

# IoMT + AR BRINGS DISRUPTION TO THE NEXT LEVEL

## Sysmex plans to use IoMT technology and augmented reality (AR) to drive operational efficiencies for both the company and its customers.

With "My Sysmex", the company's customer and service portal, field service engineers have the ability to scan an instrument, pull up the work order and ticket history of the device. Access to these tickets can be granted or denied to different users – end user or service engineer. Once a ticket has been opened, an Augmented Reality (AR) overlay displays all device-specific information. The piece that requires service is highlighted in red. Tickets include a list of symptoms and already-completed tasks. Service engineers have the ability to add/edit commentary to the symptoms if they notice any missing information.

## Sysmex is leveraging AR to increase service efficiency and ensuring consistent instrument performance in the field.

In addition, Sysmex is considering the use of digital media to provide information in real time to support staff. Service engineers may spend a lot of time figuring out the basic who / what / why of any service visit. This is now provided visually with a higher degree of precision and greater accuracy. As Med-Tech companies transition to support well-care, IoMT and AR will play critical roles.

For calibration tools developed through real time quality control, FDA regulations require companies to maintain records of maintenance activities. Sysmex is able to maintain a "digital twin" of each device in the field via PTC's ThingWorx platform.

## Utilizing the "My Sysmex" IoMT and ticketing service, the company is **effectively**:

- Improving service quality
- Reducing customer downtime
- Automating documentation for regulatory compliance
- Reducing the cost of service

Using IoMT technology on blood analyzers, service engineers can identify issues, perform calibration verifications, and predict several potential causes of short-term failure without even touching the analyzer. Furthermore, the integration of AR provides an opportunity to overlay digital data onto physical data, providing a rich visual interactive experience.

# CONCLUSION

As the healthcare ecosystem undergoes a transformation aimed at improving the quality of care while simultaneously controlling costs, the goal is shifting from sick-care to well-care by improving diagnostics and patient outcomes. From a medical device perspective, it also enables manufacturers to focus on the uptime and availability of equipment.

## With ThingWorx, Sysmex has been able to achieve the highest customer retention rate in the industry

Innovations in medical practice, products and IoMT are enabling smart connections between technology, people, processes and data that support patient centered healthcare and drive improved diagnostics and patient outcomes in a cost effective manner.

To disrupt the blood testing market, and continue its innovation pedigree, Sysmex has partnered with PTC to develop products and systems that use the latest technologies such as IoMT, AR, and analytics. The use of these technologies allows Sysmex to deeply integrate IoT into the product and the business processes using real-time data to proactively discover the need for intervention. This approach enables Sysmex to improve device reliability, monitor medical measurement precision and accuracy via quality control processes and provides evidence via data and analysis tools for targeted actions, comprising a total system solution.

With ThingWorx, Sysmex has been able to achieve the highest customer retention rate in the industry with next-generation connected product capabilities, including:

- Proactive/Predictive maintenance
- Higher uptime for its customers
- High service availability
- Meaningful, actionable data as it relates to service procedures

## The power of IoMT and AR are enabling business to not just think outside the box, but in the case of Sysmex, to go beyond building a better box in support of improved patient outcomes.

# ACKNOWLEDGMENTS

## About Sysmex

Sysmex America, Inc. in Lincolnshire, Illinois, is the US headquarters for Sysmex Corporation based in Kobe, Japan. Sysmex America distributes and supports automated in vitro diagnostic hematology, coagulation and urinalysis analyzers, reagents and information systems for laboratories and healthcare facilities throughout the Western Hemisphere.

## About PTC

PTC (NASDAQ: PTC) is a global software company that delivers a technology platform and solutions to help companies design, manufacture, operate, and service things for a smart, connected world

## About Axendia

Axendia, Inc. is a leading trusted advisor to the Life-Science and Healthcare industries. We provide trusted counsel to industry stakeholders on Business, Regulatory and Technology issues. We are honored to be recognized by CIOReview as a one of the 20 Most Promising Life Sciences Technology and Services providers.

For more information, visit **axendia.com**
Read Axendia's blog: Life-Science Panorama


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