MedLogiq

Advanced Testing Systems

Manufacturing & Lifecycle Testing for Medical Devices

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For: MDIC MEDICAL DEVICE INNOVATION CONSORTIUM

Table of Contents

Advanced Manufacturing	1
Summary	*2*
Background	3
Proven History	*4*
Resources	*5*
References	6
Core Technology	*7*
Nanokernel	*8*
Visual Authoring Tool	8
Reporting	*9*
Why Testing Matters	*10*
Components & Subsystems	*11*
Processes	*11*
Design	*11*
Product Applications	*12*
Overview	*13*
DesignLogiq	*14*
BuildLogiq	*15*
SupportLogiq	*16*
Comparison	*17*
MedLogiq Impact	*18*
Cost vs. Value	*19*
Value	*20*
Additional Services	*22*
Case Study	*23*
Generic Infusion Pump	*24*
Device Identification	*25*
Results	*26*
Integration	*27*
Contact Us	*28*

Advanced Manufacturing

Advanced Manufacturing

Summary

Maximizing quality and profitability requires thorough, accurate testing regardless of the product or its lifecycle stage. Our testing technology has been continuously developed and improved to meet evolving demands and advance manufacturing processes for over 20 years. Some of the core areas our testing platform advances are:

- Cost of quality continues to escalate
- Difficult to keep pace with new technologies
- Upgraded test parameters hard to implement
- Slow response to regulatory or market concerns
- Lack of visibility into performance or test results
- No standardization of test data or reporting
- Increasing cost of ownership to customer base

Direct Value

The result of effective testing should be easily measurable and recognizable. We have delivered these benefits to many organizations and a variety of projects, from massive global deployments to single facilities.

- Increased production quality and output
- Reduced service and warranty costs
- Less human error and headcount reductions
- Accelerated regulatory processes
- Rapid adoption of improved technology / processes
- Continuous product improvements
- Standardize testing even when outsourcing or acquiring

MedLogiq testing solutions increase profitability across operations and create industry benchmarks for quality and performance.

Background

Background

Proven History

- In 1998, our first automotive diagnostics system was implemented for Suzuki. It consisted of a runtime kernel for an existing embedded hardware platform (Suzuki Tech2), along with a new database management system called the "Visual Authoring Tool" (VAT). Suzuki used VAT to create their service testing applications, store all vehicle-specific information used to communicate with the vehicle, and to interpret the resulting test data.

- VAT is unique and not tied to any technology that can become obsolete, we have easily adapted to new operating systems and technologies changes that have occurred over the past two decades enabling customers to do the same. The system that runs on Windows 95 is essentially the same that is running today on Windows 10. Over time, many improvements have been made to take advantage of mobile computing, but the core of VAT has remained the same. An excellent core architecture evolves and adapts with technology rather than becoming obsolete and requiring building a new solution.

- VAT is an ideal solution when Moore's Law inevitably strikes. Any device with a lifecycle near 10 years is going to face many challenges as technology advances, Speed and accuracy are a tremendous competitive advantage when they are achieved reliably!

- Our test platform was the answer when this reality struck General Motors. Their homegrown diagnostic system was dated and unable to handle the latest technological advancements being added to their products. They carefully evaluated all options including building a new system themselves. After comparing the capabilities of VAT with competitors they chose VAT as their next generation test platform more than a decade ago. This resulted in tremendous increases in profitability and productivity with no fears of VAT becoming obsolete; even with the massive technology shift due to the push for electric vehicles.

VAT and our runtime platforms are robust and reliable solutions, and its maturity provides unparalleled stability and future proofing. These factors make the MedLogiq test systems the ideal solutions to advance manufacturing throughout the medical device industry,

Background

Resources

MAHLE Group

- **Top 30 global automotive supplier** and **leading test solutions partner**

Employees & Locations

- Over **72,000 employees** at **150 locations**

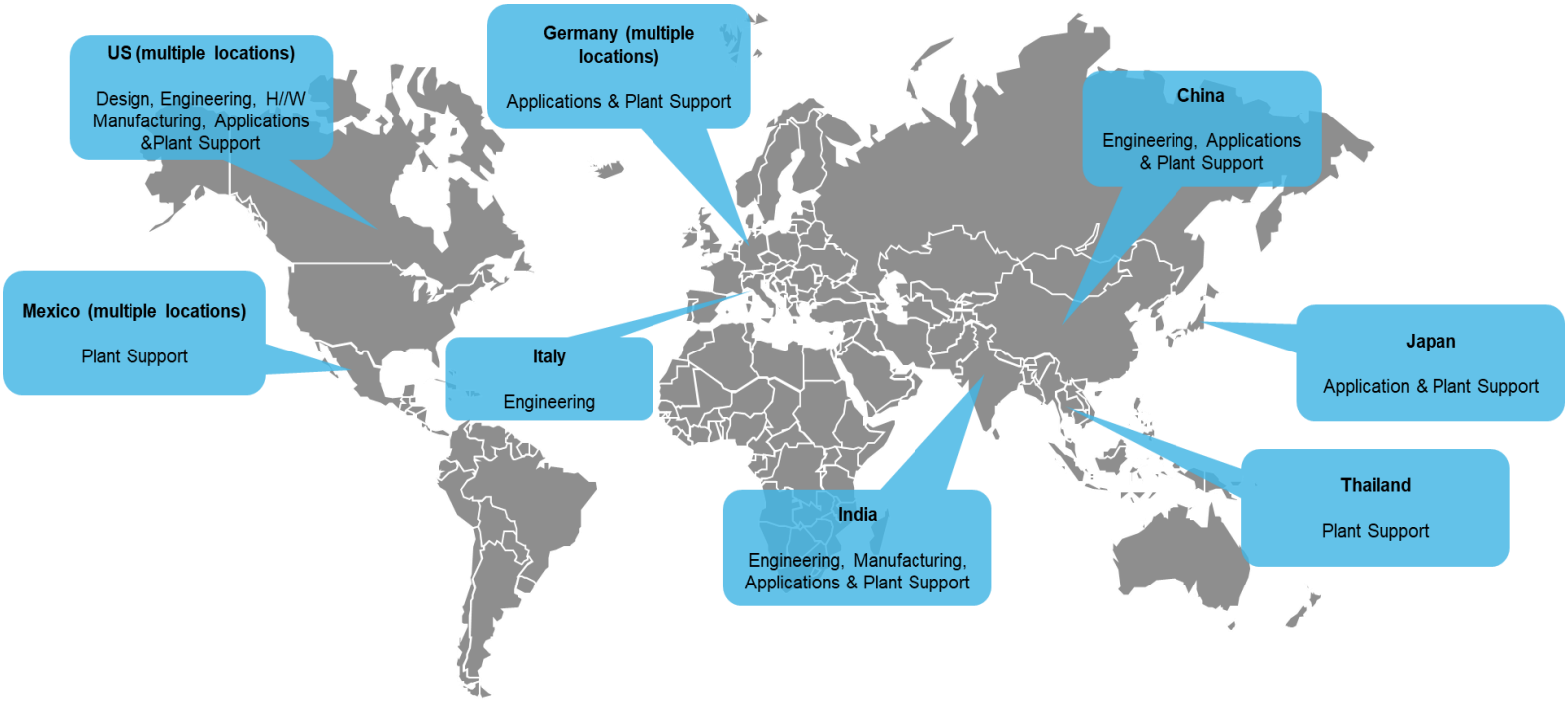
Full Engine and Powertrain System Supplier

- **$11 billion** turnover in **2020**

Driven by Research & Development

- **10 global R&D centers** with > **4,500 engineers**

Global Locations



Background

References

Since that initial service testing tool for Suzuki back in 1998, VAT capabilities have been enhanced to include diverse applications, significantly including manufacturing quality testing for Original Equipment Manufacturers.

ALL of these systems use the same core architecture; VAT, the Nanokernel, and the supporting services to integrate with OEM-specific IT infrastructure.

- General Motors' global dealership service tool (GDS2) since 2010
- Ford Motor Company global assembly plant End of Line (EOL) testing system (eCATS) since 2003
- Chrysler (under various ownerships) assembly plant Evaporative Emissions Leak Test system since 2006
- Boeing (UD DoD) Advanced command and control of multiple hydrogen powered engines for an ultra long range unmanned aircraft since 2003
- Audi (Germany) Assembly plant Evaporative Emissions Leak Test system since 2010
- Changan Motors (China) End Of Line assembly plant testing since 2012
- JMCH Motors (China) End Of line assembly plant testing and Dealership service tool since 2016
- Build Your Dream (China) End Of line assembly plant testing since 2016
- Great Wall Motors (China) End Of line assembly plant testing since 2017
- Mahindra Motors (India) End Of line assembly plant testing since 2019
- TVS (India) End Of line assembly plant testing and Dealership service tool since 2019

New Projects

Solutions are in development or scheduled for launch completion in 2022

- Daimler Truck (India) End Of line assembly plant testing and Dealership service tool
- Otosan Truck (Turkey) End Of line assembly plant testing
- Lordstown Motors (USA) All Electric vehicle End Of line assembly plant testing and Dealership service tool
- Xirgo Fleet Telematics - 2017
- Danlaw Fleet Telematics - 2018

Core Technology

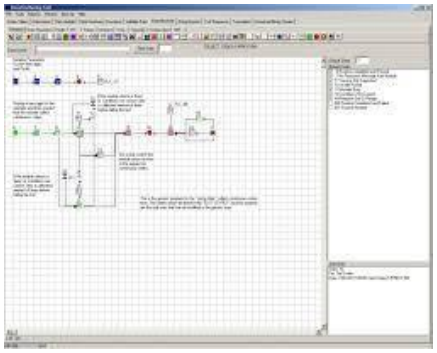
Core Technology

Nanokernel

The Nanokernel is the heart of the testing platform. It is extremely lightweight and can be run on either a shared or dedicated processer. When a dedicated processor is selected it can be in the device or externally interfaced. This allows our test system to be integrated when new products are developed or easily added to existing products. Once integrated with a device, the Nanokernel efficiently runs hundreds of tests conditionally, concurrently or simultaneously based on the OEM, customer or regulatory requirements.

Adding MedLogiq technology ensures you can test to any standard, for any condition and access test results during the entire product lifecycle.

Visual Authoring Tool



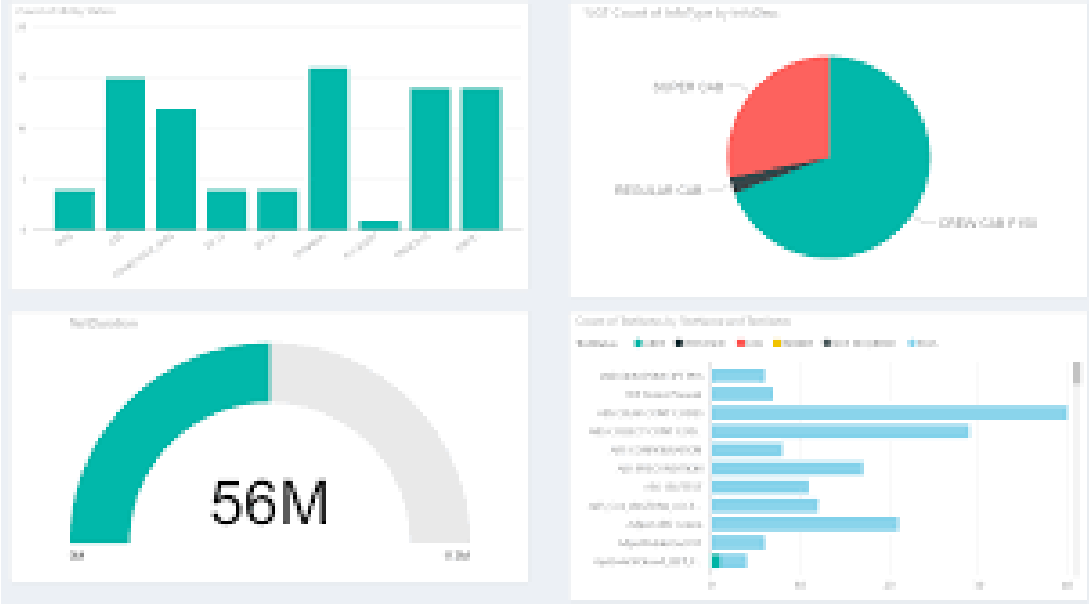
This easy to use drag and drop interface creates the test instructions that are executed by the Nanokernel. Functions make up the test elements for device states or components they will test, Tests can be run in real-time, on start-up or in dedicated test modes. They can be edited and updated as situations warrant, which is ideal for products with long lifecycles or critical uses.

VAT is proven to be invaluable when complex and evolving global regulatory standards require constant adaptation and innovation. The auto and medical device industries are perfect examples of this need.

Core Technology

Reporting

To review and interpret test data ReportLogiq was developed. This provides anywhere from a global to a granular view of test results. These reports are fully customizable and secured. They can be internally or cloud hosted based on requirements. In addition; reports can be assigned a priority level.



Test data can be reviewed or exported to other systems, vendors or regulators as necessary to automate processes and procedures.

Alerts

Alerts can be generated based on the priority assigned to the report. These alerts can be routed to assigned personnel as SMS messages or email so that critical reports are reviewed and action is taken as soon as possible.

Effective priority management and alerts provide rapid awareness and action which can save millions of dollars and more importantly, lives.

Why Testing Matters

Why Testing Matters

Components & Subsystems

A wide variety of dependencies exist when manufacturing a product that place the overall quality of the product at risk. At a minimum, component suppliers must assure the same level of quality control you adhere to. This is only more complicated when subsystems utilized and this obligation flows downstream and outside your view. It takes a commitment to stringent inbound, in-circuit, end-of-line and burn-in testing to ensure there all component limitations or failures are quickly detected. For this reason, a flexible testing system that enables you to quickly deploy new test parameters is necessary so problem components and devices are identified **before they reach the market.**

Processes

Human error also contributes to defects. The old saying went, "don't buy a car built on a Friday!" People can make mistakes and employee turnover, burn out and just having a bad day can lead to defects. Our testing systems were developed over a decade ago and eliminated the idea that a single person would be able to impact the final quality of the product. In fact, there have been numerous cases where human error has led to a design or process change that **improved the overall quality and/or throughput of products.**

Design

A design flaw is a financial nightmare, They will have less of an economic impact the earlier they are discovered. Having a powerful testing system in place at the earliest stages of development can save immense time, money which brings safer, superior products to market faster. Additionally; when a product has a longer usable life design changes are inevitable. Components and materials are continuously improved requiring engineering and design changes. It is imperative that testing is quickly adapted to validate these changes so **the expected improvements are fully realized.**

Product Applications

Product Applications

Overview

A single solution to meet highly specific needs throughout the Total Product Lifecycle.

DesignLogiq validates the product performs as expected and is worthy of investment. Problems can be identified earlier in the development process and regulatory approval timelines can be accelerated.

BuildLogiq ensures the products being manufactured meet regulatory standards and exceed customer expectations. Issues with parts or processes are identified quickly and remedied.

SupportLogiq ensures liability and costs of ownership set a new standard for the rest industry to follow. It also enables you to develop better safer products.

Think of this technology as a tool to create Benchmark tests. A tool that allows your ideal Benchmark to evolve as the market and regulatory climates mature to stay ahead of the inevitable challenges that will arise during the products lifecycle. Simply choose where your greatest need exists and expand the applications when required.

Product Applications

DesignLogiq

There's an incredible amount of time, effort and expense involved in creating a new product or even a new version of an existing product, The more efficiently a design can be validated the more quickly it can become a viable product and the more profitable it will be. However; one small mistake can have disastrous consequences, The ideal scenario is to find the inevitable weaknesses as quickly as possible to turn them into strengths and competitive advantages.

At the design and development stage a powerful testing platform is critical to foster a product through the R&D and regulatory approvals. This will lead to a new standard for quality when manufactured and reduce maintenance and support requirements. It is an essential foundation to maximize profitability and capture market share.

- Find issues early, before they can sabotage market opportunities
- Capture accurate data to accelerate regulatory approval
- Develop performance benchmarks and corresponding tests
- Measurable improvements are made in safety and quality
- Gain significant time to market and competitive advantages
- Reduce maintenance and support responsibility for user facilities
- Collect data to inform and improve development of new devices

With a proven and agile testing solution like DesignLogiq, products will be developed more quickly and profitably with significant improvements in quality and safety. It will bring operations up to the current state-of-the-art and prepare the organization for the future.

"MedLogiq embodies futuristic innovation, customer value addition and performance quality"
-Frost & Sullivan - *Future of Mobility, Excellence in Best Practices Awards*

Product Applications

BuildLogiq

The costs of poor quality continues to rise and continuous quality improvements during manufacturing pays dividends throughout the usable life of the device. Whether the manufacturing takes place in your own facility or a 3rd party site, ensuring the finished product is performing at or above its specification is crucial to the bottom line. Identifying and correcting faults caused by flaws, parts or processes immediately in any facility anywhere in the world is imperative.

Taking control of manufacturing quality and standardizing the information from all facilities provides the necessary insight to build safe and effective products and develop better one's in the future. A single platform to conduct all spot (in circuit), end of line and durability testing gives an incredible advantage. BuildLogiq provides strong value that should be deemed necessary in these market and regulatory conditions.

- Integrates into any facility, operation or system
- Rapidly adapt to market and regulatory requirements
- Validate performance acquired products with uncertain quality
- Reduce warranty exposure and maintenance frequency
- Lessen the likelihood and impact of regulatory audits
- Simplify engineering changes and minimize EOL impact
- Standardization of data with customized reports and alerts

These advantages have been realized and rewarded by Ford for supplying their global manufacturing test platform they have branded Ford eCATS. Quality and output were drastically improved while headcount was reduced by 80%.

"Congratulations for being a recipient of this coveted World Excellence Award. Thank you for all that you do in support of Ford Motor Company."
-Hau Thai-Tang, Chief Product Platform & Operations Officer

Product Applications

SupportLogiq

There are a litany of reasons to have complete visibility into product performance when devices are in the postmarket. This capability is absolutely critical in the medical device industry. Preventative and corrective maintenance are required and can be done more quickly and accurately. This can not only increase profitability but could also create new revenue streams.

Our testing platform provides all of these benefits and a great deal of value to partners.

- Drastically reduce the time required for maintenance testing
- Standardize test data from all users / facilities
- Identify defects early and with specificity
- Validate updates / defect resolution for rapid deployment
- Reduce liability exposure and increase profitability
- Predict failures and inform parts inventory requirements
- Manage maintenance schedules along entire life cycle
- Create recurring revenue streams for support services

The sum total of these benefits provides significant and immediate value. This was implemented on a global scale in surprisingly short timeframes for General Motors.

> "GM authoring environment [SupportLogiq] was deployed to global authors in November, and the dealer diagnostic system was deployed to the 4,300 U.S. Dealers on 12/12/10, achieving a $2B cost reduction over 3 years."
> - *Steven Hill, North American VP GM*

Compare your disparate test systems to MedLogiq

Feature	Contract	Owned	MedLogiq
Testing costs are amortized on a per unit basis	✓	✓	✓
Reliable, accurate testing	?	✓	✓
Complete lifecycle testing	✗	✗	✓
Standardized test data	✗	?	✓
Versatile to quickly resolve urgent CAPA and FMEA issues	✗	✗	✓
Integrate and export data to other systems / regulators	✗	?	✓
Accelerate compliance reports and noncompliance resolution	✗	✗	✓
Real-time, secure report access	✗	?	✓
Remote access to report data	✗	?	✓
Immediate alerting of important test results to key personnel	✗	✗	✓
Drive continuous improvements in existing / new products	✗	✗	✓

MedLogiq Impact

MedLogiq Impact

Cost vs. Value

Testing is often considered a necessary expense but an effective testing solution drives profitability in all areas of business. Investing in a robust, reliable and flexible test system will pay dividends throughout the total product lifecycle.

Cost

Whether the testing solution is provided by a contract manufacturer or developed in-house the expense is typically included into the BOM on a per unit basis. We provide a far superior solution with the same cost structure but with the ability to continually reduce costs and generate additional revenue. Our solution turns a necessary expense into a valuable asset and profit center. We also provide unmatched availability and visibility to your test data which becomes increasingly valuable as technology advances.

Value

Reliability

Testing failures equal product failures. Product failures lead to lost revenue, regulatory scrutiny, negatively impact brand equity and can cause patient harm. For these reasons it is crucial to ensure a test system is providing the most accurate and reliable information possible. For decades our test systems have been the choice of major global producers.

Total Product Lifecycle

The testing requirements for medical devices can seem arduous. Testing is required from the time regulatory approval is sought until the device has surpassed its useable life. Our ideal test solution creates benchmark tests that are applied throughout the product lifecycle; whether the device is being developed, manufactured, field tested or the performance is questioned.

MedLogiq Impact

Value

Resolve CAPA and FMEA issues

As with any product that requires this level of scrutiny and has a long lifecycle and critical use; understanding what went wrong and resolving it quickly and effectively is paramount. Our test systems identify these faults and validate corrective action rapidly to minimize the economic impact. This limits the financial impact of these events and creates a high level of trust with regulators and the public.

Standardized Data

Test results should be easily understood no matter which model or iteration it is, which facility it was produced in or who bears the responsibility of testing it. This way errors related to a specific supplier, manufacturing location or user facility can be quickly identified. An effective and efficient operation has all available information at their fingertips in an easily understandable format; exactly what our test systems provide.

Supply Chain Adaptability

Whether due to a pandemic, the result of component constraints or political unrest; the supply chain has been a significant challenge for global businesses. Our test systems enable you to easily adapt production at any facility to any local regulatory requirements. This enables you to quickly shift production to meet temporary or regional demands.

Shareable Data

Test data is often required to be shared with regulators, especially when problems arise. The ability to report or export test data in a preferred format simplifies the review process. It is also possible to automate reporting to reduce workload and errors and meet various regulatory requirements with our test system.

MedLogiq Impact

Value

Compliance

A device manufacturer isn't the only party with testing and compliance obligations. Failure to comply with these regulatory requirements can have serious financial implications for user facilities. Adopting our test solution creates a valuable profit center which helps ensure the device performance is validated on a predetermined interval. This creates new recurring revenue opportunities while also collecting valuable test data in the postmarket.

Data Access

Test results should be available to all that need it. Our secure, customizable portal enables reports to be created with the details important to a specific operation, department or task. The user defines the visual representation that best suits their needs to review test results anywhere at anytime. Alerts can also be set so that if testing reveals important events or anomalies the appropriate personnel are immediately notified.

Continuous Improvements

When our proven testing system is implemented there is unprecedented access and understanding of test results throughout the total lifecycle of the medical device. This improves the performance of future iterations of that device and improves the performance and reliability of new devices. There is tremendous value created by improving test capabilities and making better devices.

Additional Services

Test Fixtures

We offer design, manufacturing and installation of test fixtures. This can include fixed systems used in the manufacture of a product or portable units for field diagnostics. We have created solutions for laboratory, service center or remote testing that utilize proprietary hardware or leverage existing mobile technologies,

Test Development

We can train your engineering staff to use our simple, drag and drop Visual Authoring Tool (VAT®) for test development or do the authoring for you. VAT® is a collaborative environment and we can share responsibility or oversee authoring if desired.

Rapid Prototyping

We offer state-of-the-art prototyping and 3D printing services to validate design or engineering changes quickly in parallel with test authoring revisions. This can save valuable time getting required or desired changes into production, improving profitability.

External Testing

We can provide production testing services including fixture design and manufacturing and facilities to house them if needed. This may be utilized for durability and burn-in testing or to detect failure modes and drive product improvements. Tear-down and materials inspections can also be provided to ensure suppliers are meeting their component requirements and potential defects are discovered before they can impact customers, patients or profits.

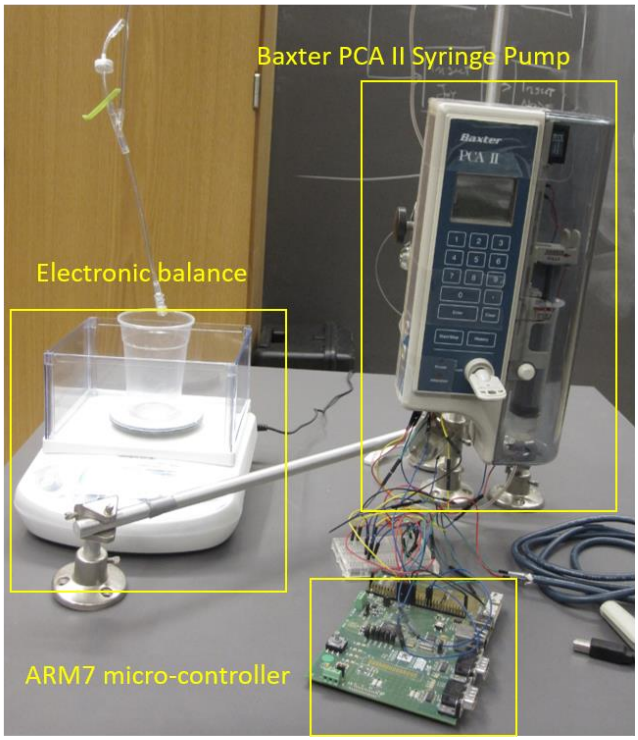
Testing Audits

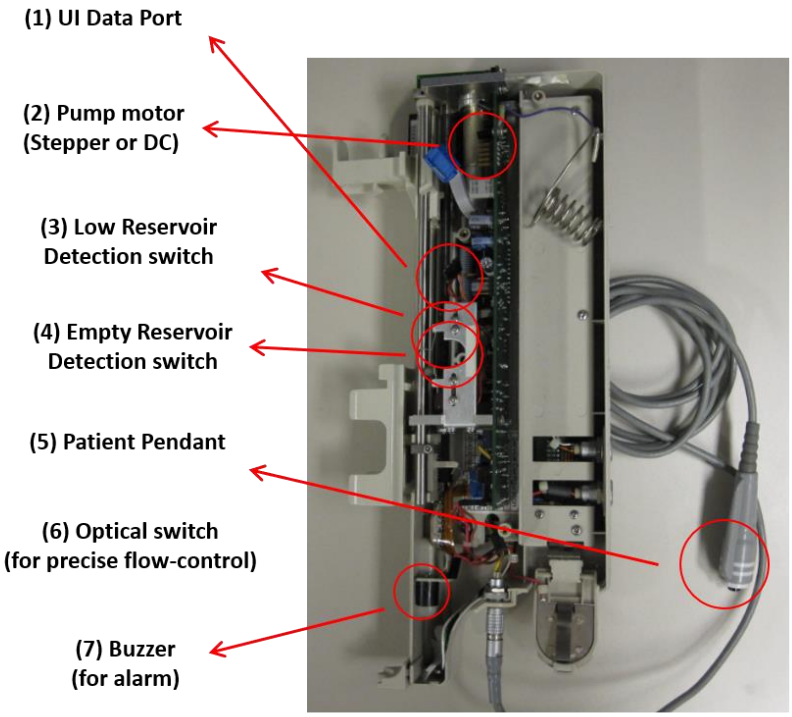
Acquisitions are common practice and it is incredibly important to know the quality of the product or company you're purchasing. When using our test systems you are almost assured the reliability and performance of those products will not be comparable to your own. We can help you determine the true level of quality that product possesses and advise on how to best integrate it into your superior test system.

Case Study

Case Study

Generic Infusion Pump





(UPENN) BaekGyu Kim, Anaheed Ayoub, Lu Feng, Linh T.X. Phan, Oleg Sokolsky, Insup Lee (FDA) Paul Jones, Yi Zhang

Due to the prevalent defects found in infusion pumps the FDA created a reference design to improve the safety and performance. MedLogiq worked with the Principal Investigators; Paul Jones of the FDA and Insup Lee of UPenn, to integrate our BuildLogiq and SupportLogiq applications. The goal was to enhance the important areas of fault detection as well as reporting and predicting failures. We also added the capability to remotely communicate performance data and define electronic (unique) device identification.

Since the device was designed and a prototype was built by UPenn, our Nanokernel was externally interfaced with via a USB port on the GIP. We then defined elements to create a more effective means of electronic device identification. This unique identification included features similar to a vehicle identification number and contains a broader range of information about the device identity, origins, key components and pertinent time related details.

Case Study

Device Identification

PID $02 Definition

PID	Description	Data Size	Format
$00	Supported PID	4	Defined in Appendix C
$01	Manufacturer Code	Variable	One Byte Length + ASCII
$02	Country of origin code	Variable	One Byte Length + ASCII
$03	Device class	1	0 - Class I; 1 - Class II
$04	Device category	6	ASCII
$05	Model Number	Variable	One Byte Length + ASCII
$06	Maintenance interval	1	Months
$07	Expiration date	10	MM/DD/YYYY
$08	Submission type	1	0-501K;1-PMA
$09	Approval type	1	0-Full,1-Temp;2-High Risk
$0A	Batch number	Variable	One Byte Length + ASCII
$0B	Date of manufacture	10	MM/DD/YYYY
$0C	Serial Number	10 (zero padded if less)	ASCII
$0D	Software Version	Variable	One Byte Length + ASCII

Additionally; we integrated higher resolution sensors in order to receive more granular performance data relating to flow rate and pressure. This was nowhere near the 2 million cycles in a typical automotive or aviation test solution but the additional data provides a greater awareness and understanding of real world device performance.

These elements provided superior data with the Black Box functionality the FDA sought when they specified a "Maintenance Processor". This functionality was desired to validate performance, simplify maintenance and store data for future analysis. Tests were also assigned priority levels so that any condition indicating a potential for patient harm would trigger an immediate alert and corrective maintenance.

Case Study

Results

We created Functions with the Visual Authoring Tool that would provide the FDA with a true performance benchmark and therefore a high degree of certainty that the device operates as designed and is safe for use. When adopting this benchmark test for end-of-line manufacturing the same level of quality is assured during production. Quality is then consistent from initial design through the devices life in the postmarket. This typically delivers increased production volume with superior quality; all while reducing costs, just as it does for large global customers like Ford.

Security of the device data is also a strong consideration and our test solutions have numerous ways to protect test data. Check sums, checkpoints and verification queries are some of the methods that can provide security and verify proper access, The design of the test with VAT and binary data make it nearly impossible to decode the information. Our solutions could actually be used to detect intrusions or prevent a device from operating in an unsafe manner.

This is all accomplished without any impact on the device software or operation. Our agile testing solution is abstracted from the firmware and software, it runs completely independently of the device. There is no added risk and altering testing parameters has no bearing on device operation or regulatory approvals. This solution will ensure software and firmware updates can be tracked and reported without causing any impediment.

There is a clear need to take control of your testing systems. Improving the quality of devices will make your organization more fiscally and socially responsible.

Case Study

Integration

Implementing our test solutions can be achieved on a large scale in a short amount of time. One of the largest projects was developing the specified tests for past and present GM vehicles with a multitude of variations for all the various makes, models, trim levels and options. This was accomplished along with the hardware development, technical infrastructure and data reporting systems within very tight timelines. The entire system went live at all 4,300 North American service locations in just 8 months, It was then deployed in the appropriate languages at all global service locations in the following two months. GM engineers were also trained during this time and continue to author some tests with VAT.

For comparison; we developed the functions, tests, and completed integration with the Generic Infusion Pump in 6-9 months. This included test authoring, wired and wireless communication, electronic device identification and a revised reporting system. The estimated costs for this project were $75K - $125K. Embedding our technology or different hardware / software requirements may impact the total cost but can significantly increase the value.

Timeframe = 6-9 months
Expense = $75-125K
Note: Some work was also performed by Precise students at UPenn

It's clear that the medical device industry lags behind other advanced products and industries in performance awareness and innovation. We have successfully adopted applications created to advance and prepare the auto and aviation industries for the future with medical devices. Though the number and resolution of data sources may be considerably less with medical devices, there is no product category where quality and performance are more critical. The dependency on medical devices continues to expand and reliability must keep pace. We have countless applications that are proven to help organizations do just that.

Contact Us

To learn more about how MedLogiq can enhance product manufacturing and improve ROI reach out to us at:

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Email : advman@med-logiq.com

To learn more about the broad range of proven solutions available to transform your business click on the link below: