

Rapid Feasibility – Molecular Diagnostics System Concept in 2 Months

The Starting Point

The global molecular diagnostics market is projected to grow at a Compound Annual Growth Rate (CAGR) of 8.4% by 2023¹. An increasing prevalence of infectious diseases, e.g. new forms of influenza and severe acute respiratory syndrome (SARS), is driving the demand for new accurate diagnostic instrumentation with an emphasis on faster detection to fight the early spread of these infections. Not only does this apply to the In Vitro Diagnostic (IVD) market, but also for the food and beverage market. In 2019, a European market leader in the food and beverage market requested BIT to create a design and development concept for their next generation PCR instrumentation, as their first-generation device was facing obsolescence issues due to outdated technology. In addition to obsolescence, their goals were to improve the overall robustness, reduce cost of manufacturing, update the connectivity regarding IoT, and create a modern user interface.

The Client Challenges Faced

- Creating Robust Design with a Small Footprint and Decreasing Manufacturing Costs**
 The first generation of the instrument was developed over ten years ago and was not designed to meet the required cost structures for the intended market. The challenge was to develop a more robust system architecture that will generate cost savings in manufacturing while keeping the small footprint and allow flexibility for different functionalities. The client recognized the added value of outsourcing the development work to a partner with deep expertise in systems engineering and other cost-saving engineering initiatives, such as Design for Manufacturing (DFM).
- Missing In-House Knowledge Regarding IoT**
 The European client did not have adequate in-house capabilities in terms of software and firmware development for Internet-of-Things (IoT). The goal was to allow easy data sharing capabilities between the different modules and a cloud network to create a real-time data analysis system while maintaining industry-standard security and compliance with regulatory bodies.
- Increasing Serviceability and Obsolescence Management**
 The client’s instrument was originally not designed to meet the demands on low service costs and had different serviceability issues. One major cost driver was the need for a qualified field technician to service the complex instruments on site. The goal was to leverage DFM and Design for Service (DFS) to identify future cost drivers (parts and labor) early in the development process.

The Results



¹ Molecular Diagnostics Market by Application - Global Forecast to 2023." Markets and Markets, www.marketsandmarkets.com/Market-Reports/molecular-diagnostic-market-833.html?clid=CjwKCAjwztL2BRATEiwAvnALck79WTJJ1Ohe74IM-MFQhlarX6WjaE7iD6x3htSX2h-jliiviYLNi4xoCmd8QAvD_BwE (May 30, 2020)

BIT's Solutions

- Proven Expertise in Developing a Smart System Architecture to Generate Cost-Savings**

BIT developed a smart system architecture which was based on a modular magnetic plug and play approach to allow flexible configurations. The design incorporated one common housing for all modules, regardless functionality (e.g. control unit, PCR, fluidic system, and power). This modular design easily allows the addition of multiple PCR units, giving BIT's client flexibility in throughput as well as the flexibility to perform different assays simultaneously. In addition to modularity, the architecture and its components (e.g. versatile optic module supports multiple wavelengths) are flexible enough to allow future adaptability to other markets and their technologies, such as immunoassays in molecular diagnostics and life sciences. Through these design decisions, BIT increased the overall robustness of the system, which ultimately enhanced the reliability and consistency of the device. In addition, BIT generated cost-savings through the reuse of parts, which cuts labor costs in manufacturing through more efficient assembly processes (Design for Assembly).



- Leveraging Software Development Capabilities to Enhance Connectivity**

At the beginning of the system architecture design, BIT introduced a cloud infrastructure to lay the foundation for IoT and enable data sharing. The main advantage is the client can now leverage their device to remotely analyze testing data in real time. As a result, no physical proximity between patient, sample, doctor, and laboratory is required. Another advantage for the end user was achieved by creating an innovative software concept that is independent of the device. Any smartphone or tablet can be connected via Bluetooth and used as the user interface. In addition, the ability to run the instrument on a rechargeable battery opened the market for decentralized testing in developing countries and military operations around the world. In summary, moving common user interactions such as data storage, configurations, and algorithms to the cloud not only reduced the instrument's footprint and costs, but also significantly improved the functions and advantages for the end user.

- Instrument Exchange Model - Minimal Instrument Maintenance**



The challenge was to reduce the prior high service costs and increase the overall serviceability. After performing a DFM analysis, BIT created a simplified design based on more standardized components with well characterized reliability. The result was an increase in product quality while minimizing potential risk factors for the instrument that could lead to high maintenance costs. In addition, BIT developed an innovative service concept for its client which was based on "swap service offering", allowing their users to switch out broken modules with a box to box exchange model. This allows our client to have corrective maintenance and preventative maintenance performed by the operator and it does not require a trained field-service engineer to visit the unit in person. With this innovative service model BIT was able to significantly reduce the involved service costs for its client.

Why BIT?

- 150 Engineers and Scientists Holding over 30 Internal Patents** - Systems, Software, Electronics and Mechanic Engineers with a vast knowledge in a broad variety of technologies receive continuous updated training in spaces like market regulatory requirements, risk management and design processes to ensure they are leaders in their space. Our patents can be utilized by clients to accelerate time to market and to add additional beneficial features to their products.
- 43 Years of Excellence with More Than 190,000 Instruments on the Market** - Our competency is evident in our long-term manufacturing relationships with industry leaders like Siemens, Abbott, Beckman Coulter.
- We Speak Regulatory** - With an in-house regulatory team and all BIT manufacturing facilities operating under ISO 13485 and FDA certifications we ensure our customers are planning and achieving all relevant regulatory requirements.
- Long-lasting Team Collaboration** - We have over 95% full-time employee's with low turnover rates and long work relationships in our engineering and manufacturing department. This allows working together with a stable and consistent project team throughout development and manufacturing.