

Biomedical and Diagnostics Overview

Boston Engineering solves complex product development and engineering challenges for bi-therapeutics, diagnostics, and medical devices organizations. Our multidisciplinary teams combine innovative thinking with the technical and regulatory experience to drive product success.

Boston Engineering applies its phase-gate development process to:

- Mitigate risk
- Optimize for manufacturability and service
- Comply with stringent regulatory requirements
- Accelerate time to market

Our Impact: Improving Health with Rapid, Automated Testing

Background: A major diagnostic healthcare manufacturer entered the consumer health market as its rapid flu test advanced to pilot production. The existing design had limitations including limited software updates to read new strains, cartridges, etc.

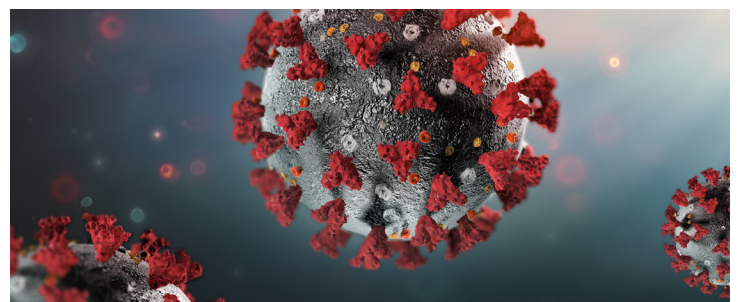
Approach:

- Early concept through final regulatory stages
 - Concept designs, design for an alpha prototype, test equipment, production ramp-up, testing, regulatory documents, etc.
- Developed a miniature fluorescence reader compatible with existing disposable design
 - Bluetooth connectivity
 - Image capture & analysis
 - Mobile app
- Design for manufacturability, cost, etc. (DFM&A)
 - Design for use with varying cartridges – accommodate various sized cartridges and diminish ambient light



Our Impact:

- Advanced from proof-of-concept to pre-pilot manufacturing
- Emergency use authorization (EUA) approval



The Boston Engineering Advantage

Boston Engineering develops novel technology for commercialization that improves how people work and live. Examples:

Precision:

- Example: Generate samples 20 nanometers thin – the equivalent to slicing the width of a human hair into 4,000 sections

Automation and Performance:

- Cut testing cycles from months to days, or days to hours
- Automate and control manual research processes that are slow and costly
- Enable sophisticated sequencing, timing, and prioritization
- Run experiments 24/7 for weeks
- Maintain precise temperature, environmental requirements

Diagnostics:

- Laboratory and point-of-care applications

Biomedical Engineering:

- Design for manufacturability and assembly (DFM&A)

- Integrate novel technology with commercial-off-the-shelf (COTS) products to accelerate development, reduce costs
- Micro fluidics: dispense, handle, and transfer
- Thermal management and control
- Kinematics modeling (control systems)
- Software and GUI development

Connected Capabilities:

- Internet of Things (IoT)
- Augmented Reality (AR)

Compliance:

- ISO 13485:2016-certified design control procedures
- ISO 9001:2015-quality management systems
- Application of device design standards including IEC 62304, IEC 62366, and IEC 60601

About Boston Engineering

Boston Engineering provides product design and engineering consulting from concept through commercialization and connectivity.

Certified for ISO 9001 and ISO 13485, the company's industry expertise includes commercial, defense, and medical. Founded in 1995, Boston Engineering is headquartered in Waltham, Mass.



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