# **Ə Thermo**Fab

## ADHD Testing Unit Transformed from Clunky Cubicle to Dashing Chariot

**BioBDx Turns Revolutionary Concept into Reality with Proper Design, Timing,** and Budgets



### Challenge – Ensuring That Product Innovation Doesn't Fall Victim to Inflexibility, Delays, and Unnecessary Expenses

Revolutionary medical products still need the manufacturing and economical flexibility to evolve. Getting a product's look, feel, and mechanics to be "just right" sometimes takes several trials. If these "trial and error" periods become too cost-prohibitive or time-consuming, it's possible that a truly innovative product could be abandoned – and for all the wrong reasons.

Massachusetts-based BioBehavioral Diagnostics Company (BioBDx) faced these challenges when developing the Quotient<sup>™</sup> ADHD System, which is the first FDA cleared system<sup>1</sup> that offers medical professionals an office-based capability to conduct rapid, precise, and objective patient assessments to aid in the diagnosis of ADHD.

In terms of design, the original developmental unit was similar to a library cubicle. It had a large footprint and exposed wires, and it was a bit cumbersome. Mechanical issues included too many parts that could possibly vibrate (something that could potentially skew results), too much manual operation by medical professionals, and problems associated with unit assembly. BioBDx wanted a design that would appeal to children and adults, a product that doctors and nurses would find easy to use, and a unit that had straightforward assembly.

#### Solution – ThermoFab provides Project Management and Manufacturing Expertise in Redesigning Quotient<sup>™</sup> ADHD Test System

BioBDx contracted New Hampshire-based Farm Design, "a full-service, FDA and ISO compliant product development company," to rework the look and feel of the kiosk, which went from library-corral boring to Roman-chariot chic, and to ensure that issues, such as the vibrations, were minimized. ThermoFab worked closely with Farm Design to ensure that this dream concept transformed into reality – and that the design still had enough



#### Result

BioBDx's innovative medical product is already aiding clinicians in the assessment of ADHD.

ThermoFab has manufactured components for more than thirty Quotient<sup>™</sup> ADHD Systems, which are currently being beta-tested in the Atlanta marketplace, with more units in the pipeline. While the beta launch is likely to result in suggestions for modifications, BioBDx knows that ThermoFab can swiftly and economically make these design modifications, thus ensuring fewer delays as this important product is made more widely available, shown at trade shows, and demoed for medical organizations.

Speed, quality, cost-effectiveness, and flexibility, what more could you ask for? flexibility to accommodate changes down the road and that it could be swiftly constructed by ColumbiaTech, the contract manufacturer secured to assemble the unit.

BioBDx Director of Product Development, Ken Hoadley, said, "We knew there were going to be design changes along the way, and we wanted someone who was flexible. ThermoFab easily fit into the mix. They offered assistance with design features for manufacturability to minimize costs and complications in getting this built."

In addition, ThermoFab assisted with project management. Hoadley noted, "With so many 'partners' involved – Farm Design, ColumbiaTech, ThermoFab, and us – ThermoFab's Michael Wahl and his team offered their expertise in organizing and planning the steps we needed to take to bring this to market. They helped us coordinate the efforts of the three companies to handle parts and ship them back and forth. They were involved in transportation and assembly issues. There were multiple hand-offs along the way, and ThermoFab stepped in when needed to provide direction and discipline."

 $^{\rm i}$  The FDA has cleared the Quotient ADHD System for marketing through a 510(k), which clearance permits the product's sale in the United

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