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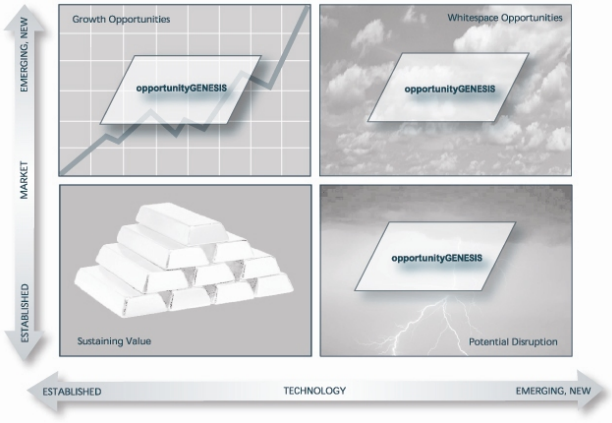
Opportunity Genesis: Technology Scan™ Establishes Realistic Architectural Boundaries for Clinical Assessment Device

Client: Leading manufacturer of clinical assessment and therapy devices.

Challenge: The client identified an opportunity to develop a very low cost personal self-diagnostic device that could improve how prophylactic pharmaceutical therapy was self-administered by patients. The conceptual device required integration of a dynamic patient performance parameter over time. This presented a greater design challenge that the static measurements their products had historically recorded. As a further technical challenge, the client had strong expertise in manufacturing mechanical devices, and was extremely reluctant to develop electronics manufacturing expertise for this opportunity. Before a full development program could be initiated, the client needed to understand what the performance requirements were, what technologies existed, and whether it was possible to meet the required performance goals with their manufacturing capabilities.



Diagnosis: The client had an excellent understanding of the market, including the basic requirements of cost, ease-of-use, and portability. At the time, there were a large number of high-end electronic devices for in-hospital use on the market. These multi-function, multi-user devices cost 20-30 times the target cost of the single-user, single-function conceptual device.

The assessment advantages of the measurement to be taken on the patient were very well documented and broadly accepted as the gold standard for in-hospital use by clinicians. Furthermore, the parameter measurement was extremely well defined by industry standards, including different ratings for the quality of the measurement.

This was a somewhat unusual case for a conceptual product, in that the benefits of the product were well understood and accepted, and for the most part, the performance requirements were extremely well defined. The primary challenge would be cost. The client's historical solution and core capability was to use in-house injected molded mechanical assemblies. The client needed to know if this approach would work in this case.

Methodology: Product Genesis applied our proven Technology Scan™ to this analysis. We began with collecting information on the assessment measurement. While background on how a patient would make use of the device out of a clinical environment was insightful, the most valuable information in this case was information on the assessment measurement itself. An industry self-regulatory body had established detailed requirements for the measurement, along with a portfolio of patient profiles that device performance would be evaluated with.

In the next step we reviewed the technologies used in the high-end products and the associated literature, including patents. This background material was the foundation for concept development focused on low cost measurement of the assessment parameter, which included two key elements: the dynamic element and time measurement. As a practical matter, the concept development included both mechanical and electromechanical solutions. Using criteria developed with the client, these concepts were down-selected to a smaller set of the most promising concepts.

Models of the leading concepts were developed based empirical and analytical activity. The standard portfolio of patient performance curves were fed into these models to determine how well the low cost approaches could provide the assessment parameter. In addition, complete bills of materials, with tooling costs, were developed to better understand the costs associated with each concept. Based on this more thorough investigation, one purely mechanical and one electromechanical solution were down-selected, although the latter was clearly the more accurate and cost-effective solution. To reinforce the negative attributes of the purely mechanical solution, a prototype was designed and implemented using low-cost off-the-shelf components.

Results: The Opportunity Genesis process helped the client develop a more complete understanding of the technological hurdles associates with this market opportunity. In this case, the investigation revealed the fact that the client's present technology portfolio would not allow a marketable product to be developed. Rather than develop electronics manufacturing expertise at that time, the client chose to terminate this program and focus on projects more in line with their capabilities. Approximately 2 years after this decision, a different company independently introduced an electro-mechanical device to meet the identified need.