WHITE PAPER

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Managing the Complexity of **Medical Wearable Development**

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Introduction

Wearable healthcare devices comprise an expanding new market with enormous long-term potential for breakthrough products.

Recent research[1] reveals that roughly half of U.S. households with a broadband connection now own a connected fitness device, such as an activity tracker, pedometer or sports watch. A quarter own a connected medical device, such as a smart thermometer, a connected blood-pressure reader, or a cardiac monitoring device.

Given that the number of devices per household has tripled in the years 2018-2022[2], the sizes and growth of the wearables market makes it attractive for engineering teams who can introduce a new biometric or method.

Products related to the medical field, however, differ in many ways from typical consumer electronics in both design and execution. At the outset, new entrants need to know the hurdles of bringing a high-tech medical device to market.

This white paper explores the multiple complexities of wearable product development, using the example of a common wearable, a personal use continuous glucose monitor (CGM).

Examining the construction of this diagnostic device reveals the areas where co-optimization and system-level innovation can solve the numerous engineering challenges that arise on the way to market.

[1] https://www.prnewswire.com/news-releases/parks-associates-46-of-us-broadband-households-own-a-connected-health-device-300688364.html

[2] http://www.parksassociates.com/report/connected-health-state-of-market

An Engineering Problem Across Disciplines

Despite the outward appearance of simplicity, a slim, single-function device can represent a complex set of design considerations.

Personal healthcare devices bring together numerous technologies, several dissimilar materials and interfaces that must be understood and operated by a wide range of users.

These many aspects require expertise across several design and production disciplines, some far afield from the skillsets that generated the original invention. Beyond engineering subdomains, the incremental gains in lightweight remote devices over the last decade have increased the sophistication of design-for-manufacturing (DFM) and design-for-assembly (DFA) techniques that have proven essential for success in the medical arena.

Fostering collaboration across these many disciplines could be referred to as co-optimization. If one component or subsystem were to be optimized by itself too early in the process, it may turn out suboptimal for the overall project.

Holistic development balances the needs of all the nested interacting subsystems as well as the time and cost demands of production. It relies on a big-picture understanding of the various tradeoffs in play.

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The Hidden Complexity of a Medical Wearable

Imagine a no-frills prototype which succeeds in detecting a biological stimulus and outputs a digital signal. This version, formed from off-the-shelf components and basic controls, might work to prove the concept, but would lack the compactness, durability and intuitive user controls needed for in-the-field operation.

If history of the industry is any guide, it would typically take about two years to develop this proof of concept into final form, ready for use with patients. What design attributes does this new concept need to acquire to transform it into a mass-produced wearable medical device?

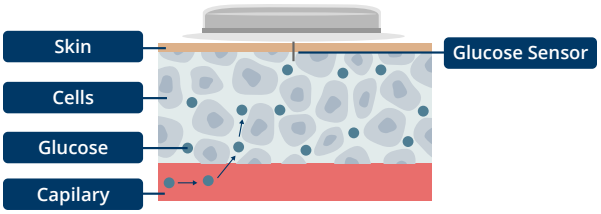
- **Durability** – the device needs to withstand the knocks that come with the motion of the user—and an occasional drop on the floor—without damage to the instrumentation or effect on data. This may require some of the structure to have rigid materials. Because the outer shell must be resistant to moisture and debris, precision injection molding on both rigid and flexible materials are needed to ensure tight seals.
- **Size and Weight** – standard-size components are often replaced by new miniaturized forms of electronics, antenna, and microprocessors to reduce weight and bulk. In many cases, the choice of power source or battery dictates the size and form factor of a wearable.
- **Usability** – For an item that is attached for several days, the outer materials would consist of an elastomer or similar soft material for comfort, or the entire wearable might consist of a nonrigid substrate, as is the case with newer flexible electronics. Usability can also refer to the simplicity of the interface, which must be easy enough for a nonprofessional to operate.

- **Biocompatibility** – As per regulations, materials that contact a patient's skin, delivered intravenously, or ingested must be made from specially designated materials to avoid irritation or toxic effects.
- **Data System Compatibility and Compliance** – medical data needs not only a robust signal on the hardware side, but also compatibility with the designated medical software systems to ensure privacy.
- **Reliability** – the source of power needs to be adequate for the period the device is expected to be worn—15 days in the case of a CGM—or else have a user-affable method of recharging. Power should also meet the thresholds for reliable connectivity.

Subsystems of a Continuous Glucose Monitor

Many of these attributes can be seen in this recent CGM product. The two-part monitor consists of a coin-sized puck that adheres to the patient's skin and transmits to a user-operated receiver.

A CGM measures blood glucose levels over time and is an improvement over the previous generation of conventional blood glucose monitors (BGMs) that only provide a few discrete data points. Users gain a clearer picture of their glucose trends in response to dietary intake and physical activity throughout the day.



View of CGM puck with glucose sensor.

A glimpse inside a CGM would show the wide diversity of specialties involved.

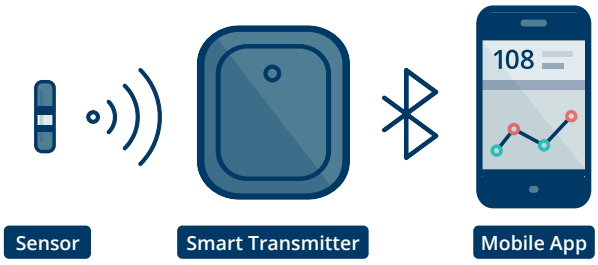
The PCB assembly (PCBa) employs a tight layout of miniaturized components surface mounted with automated soldering. The circular board includes a microprocessor, near-field antenna, battery, thermistor, and enzyme sensing pins. Specialty manufacturing for the disc requires extensive quality control, including rounds of visual, software and x-ray checks.

Any biodata collection device will demand precision mechanical parts of various materials. This CGM required tooling for single-shot, insert and 2-shot molding for rigid plastic housings and actuators. Once molded parts are made, related processes might include coatings, like low-pressure mold encapsulation and precision stamping.

Separate factory processes generate soft elastimer-molded components for the seal. Also, biocompatible material is used in the subcutaneous placement cannula. Some sensor components require sterility during manufacture, requiring outsourced facilities for clean builds.

In the case of this CGM product, the appropriate adhesive material was needed for the puck to stick to the skin for a two-week period, exposed to water and wear.

Then there are the systems common to nearly all medical diagnostic hardware: power management optimization, micro I/O connectors, as well as compliant data processing, connectivity, and software development.



Connectivity of a CGM system.

Central Challenges in CGM Development

This development project enlisted a contract development and manufacturing organization (CDMO) for advice to help solve several design problems. In the case of the CGM, the consultancy aided in these key areas:

- **Ingress Prevention (IP)** – Preventing liquid and dirt ingress through a sealed encasement which combines soft- and hard-molded plastics.
- **Miniaturization of the Electronics and Mechanical Package** – Ensuring high-quality functionality of electronics and mechanics while fitting into a space of just one cubic inch. Specialty micro-connectors, consolidated antenna and precision surface mounting condensed the size of the hardware.
- **Design for Production** – Strategic design changes to shorten time to market, for example, utilizing automated production techniques, or simplification of structures to reduce manufacturing and assembly costs.
- **Design for Assembly** – Anticipating problematic assembly issues, such as preventing damage to batteries from improper sequence of system connections.
- **Certification Process** – Preparations to pass design verification and testing .
- **Sourcing and Scheduling** – Establishing global supply chain capability and monitoring of day-to-day production status.

A CDMO can assist with its engineering personnel, industry network and in-house production facilities. Outside design teams receive access to experts who have developed a wide range of medical device products according to DFM and DFA best practices and can make use of co-optimization among proven vendors. This assistance is often needed to avoid the pitfalls that can derail project timelines and can also enhance the value and competitiveness of the final offering.

Co-Optimization Brings Production Issues to the Foreground

The problem that arises when hiring many independent manufacturing partners is the lack of coordination or free-flowing collaboration among the specialized groups, especially if some of the contractors are not necessarily well versed in medical applications.

A specialty vendor in injection molding may know how to optimize design changes for in-house manufacturability but remain unaware of how those adjustments could affect the other, closely stacked subsystems.

On the other hand, if a simple information exchange is established, design changes and tradeoffs can be analyzed and negotiated. These arrangements among engineering teams make co-optimization possible.

A vertically integrated design, development and manufacturing contractor can engage in agile cross-communication. The concept design team can discuss their plans with experts in all critical areas, from regulations and standards and software development to part tooling, assembly and packaging.

Taking a system-level view brings the later stages of commercialization into the foreground at the initial stages, especially when considering such definitive issues as power management, form factor and material selection.

Advantages of System-Level Design Strategies

A reduction in part count or other means of simplifying the subassemblies can take advantage of industry-leading high-volume automation solutions to lower downstream costs and shorten timelines.

In other cases, implementation of best practices and quality engineering simply cuts down on loss, waste, and mistakes. Final assembly of the subsystems at the factory, for example, needs careful planning. Delicate components are liable to break if inserted in the wrong order. A battery inserted improperly can lead to power drain and premature failure in the field.

In the CGM example, trading out the antenna for a condensed, printed version from Molex that wraps around the circuit board frees up more space while still managing a robust signal.

Co-optimization with an eye for cost and timeline efficiencies can sidestep many of the typical tradeoffs. Designers can boost a capability by a margin without having to sacrifice in the areas of power, space, or cost.

With the proper coordination, these efficiencies can add up. Managing the complexities of design and development through a CDMO partnership can lead to a more affordable, more effective, and more commercially successful medical wearable.

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