

## ***In Vitro Diagnostics Test Strips Require Optimized Interconnects and Automated Assembly for High Volume Production***

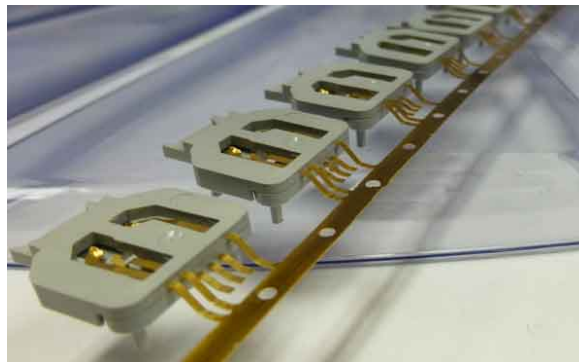
The In Vitro Diagnostics testing segment has rapidly become one of the prominent sectors in the overall Life Sciences & Medical industry. Led by sales of glucose monitoring test strips, sales have exceeded \$13 billion in 2015 and are expected to reach \$18.5 billion by 2020.

Due to the disposable nature of test strips, the interfacing interconnects of the meters that read the strips represent a significant technical challenge to achieve the volume production levels, consistent and stringent quality control requirements and low-cost assembly that are necessary to succeed in this segment.

This Tech Bulletin outlines the basics of test strip interconnect design and shows how advanced manufacturing methods combine continuously stamped leads, reel-to-reel over-molding, fully-automated inspection and assembly to enable cost-effective high volume production of interconnects.

### **Test Strip Design Basics**

In Vitro Diagnostic test strips are made with a variety of technologies such as electrochemical and photometric, with the majority using electrochemical technology. Electric current from the meter is carried through a rigid mating component (the interconnect) to the embedded circuits of the test strip when it is inserted into the meter. The meter's processor and software turns the data received from the test strip into a numerical reading.



The Interconnect

Test strips and their meters must conform to international standards. These include ISO: 15197:2013, which specifies blood glucose accuracy requirements and ISO 13485:2016 that mandates manufacturing quality management requirements for medical devices. In addition, the interconnects that mate with the test strips need to be sufficiently rugged to withstand the demands of consumer usage under diverse field conditions without compromising the delicate enzyme sensing functions embedded on each strip.

The interconnect design that mates with the test strips represents a critical factor for success. Careful attention must be paid to the electrical and structural parameters as well as the inherent variances of individual consumer use while using a Design for Manufacturing (DFM) approach that minimizes cost and optimizes consistent manufacturing through automated assembly.

The following sections describe how a continuous manufacturing, assembly and inspection approach can help In Vitro Diagnostics companies meet these goals.

### **Component Design and Continuous Manufacturing Processes**

The stamped interconnect element that mates with a test strip serves both electrical and mechanical functions. It provides the electrical interface from the strip to the meter while providing the rigid mechanical structure needed to support and protect the delicate enzyme-based sensor. The proper design of this component is complicated and challenging. The design has to assure consistent electrical contact with the strips so the meter readings are consistent regardless of user variability. It also must provide tactile feedback to the user thereby giving it the required “feel” or pressure that illustrates a successful connection has been made. The latest design tools utilizing finite element analysis modeling and mold flow are used to quickly model design iterations to reduce development time and ensure the achievement of design goals.

The process of designing interconnects incorporates the latest design for manufacturing techniques where components are all designed within the parameters of the planned manufacturing processes. This results in very consistent manufacturing processes. High volume interconnect manufacturing are continuous processes where all of the components are fed onto and removed from stamping presses and molding machines using a reel-to-reel format. This provides a highly efficient and repeatable method for cost-effectively creating these electrical and structural elements in high volume (See below).

After component design and prototyping, the first step in the manufacturing process is to stamp the parts on a continuous strip that is fed from and taken up by reels. These reels then feed the next process step where the stamped insert is over-molding. Plastic housings are molded over the stampings to encapsulate them and to provide proper mechanical support for the test strips and connections within the monitor. For multi-part designs, it can be very useful to stamp the parts in dual rows and then to conduct a dual-molding process on the stamped parts while they are still in the continuous format. This simplifies overall production, minimizes secondary processes and assures

uniform results. It also keeps the molded parts in a format that optimizes automation in subsequent steps (See Below).



Dual Insert Molding

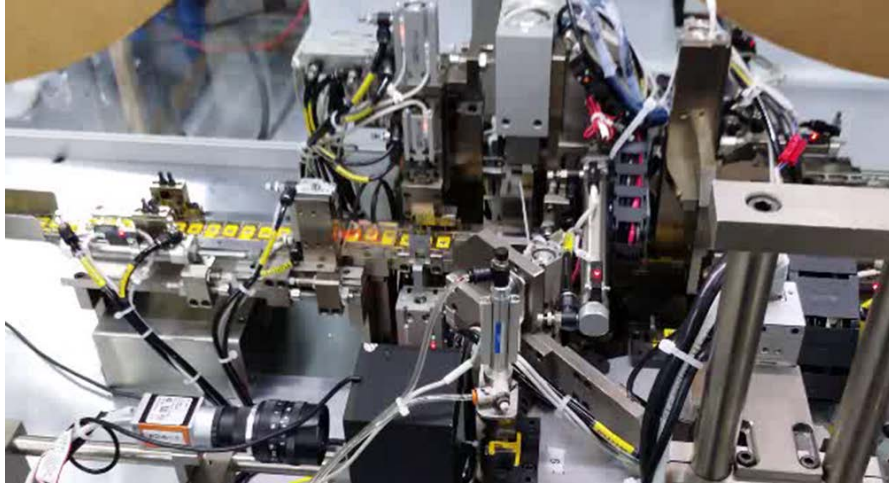
### **Continuous Automated Assembly & Inspection**

The reel-to-reel continuous format also efficiently supports subsequent assembly steps, such as stitching together two dissimilar parts to form the completed assembly (See below).



Two Dissimilar Strips – Stitched Together

Finally, because the completed parts are still in the reel-to-reel format, they can be inspected using automated processes to check for key quality factors, including continuity, opens, coplanarity, dimensional conformance, defects, etc. If required, this automated system can then separate the final parts for tape and reel packaging of individual components.



Automated Inspection and Packaging

**Summary:**

For designers of In Vitro Diagnostic equipment that uses test strips, the ability to leverage an ISO 13485 certified assembly partner with deep experience in designing, developing and providing continuous, automated turnkey test strip interconnect manufacturing can significantly reduce costs while meeting high volume production and stringent quality requirements.

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