The True Cost of Packaging

SCIMETRIC MEDICAL SOLUTIONS

Challenge

The importance of an effective, repeatable and reliable sterile sealing process for medical device packaging cannot be overstated. And yet, in many cases, it is the last consideration of the manufacturer as they bring a new product to market. This is despite the fact that a packaging failure will often require the part to be re-sterilized and repackaged, or even scrapped if this is not economically justified. In the worst case, if the sealing error is not detected, the ensuing contamination can lead to discovery at the end user, which can trigger costly recalls. Therefore it is essential that the manufacturer develop a packaging process that is 100% reliable and repeatable.

Solution

The conventional approach to ensuring the quality of the packaging process relies on the destructive testing or manual inspection of a sample of packages from each production lot. An alternative approach makes use of Sciemetric's process signature verification technology to monitor package quality on each and every package. By catching the defective packages as they are being made, we can virtually eliminate failures at the downstream destructive test. In the long run, this may enable the manufacturer to eliminate the need for destructive testing altogether. In addition, this technology provides real-time feedback on the packaging process itself, so that the manufacturer is able to quickly identify and implement corrective actions, without having to wait until the samples have passed through final test. Finally, the test data can be stored to provide a permanent record for traceability and proof of compliance for every single package.

FEATURED SOLUTION TEST COMPONENTS

sigPOD

- Compact configurable test system
- Up to 8 analog inputs
- Easy-to-use Graphical User Interface
- Optional touch-screen display
- Multiple interface to communicate with control systems and enterprise software

QualityWorX Software

- Proof of compliance
- Part-by-part Traceability
- Process Developments
- Process Control
- Defect Detection and root cause analysis

the science of quality

Let's consider a recent example where a manufacturer was looking for a means of ensuring a quality seal in a heat-sealed package. Heat-sealing is commonly used in tray sealing, thermoform packaging, pouch sealing, clamshell packaging, breathable pouch sealing, and more. Although these span a range of product and package types, the basic sealing process is the same in each case. There are three key process parameters that determine the quality of the seal. These are: the temperature at the sealing interface, the pressure or force applied to the sealing area, and the dwell time. Too often one or more of these parameters is not properly monitored or controlled, resulting in a wide range of process variation, and a low packaging yield. For example, non-uniform thermal profiles, sealing gasket wear, mechanical misalignment, or dwell-time variation can all produce defective seals. Ensuring that each of the three parameters is maintained within the desired ranges for each and every package is the key to ensuring a proper seal.

To begin, the temperature profile across the sealing interface was measured by an 8-channel sigPOD™ configurable test system. Next, the applied force was measured by the same sigPOD unit to provide an accurate, high resolution measurement of the pressure at the sealing interface. These measurements were synchronized with the readings of the temperature profile, to create a series of curves or *waveforms* consisting of temperature vs. time and force vs. time. The dwell time was then determined by configuring the sigPOD to measure the length of time during which the applied force and the temperature profile were within pre-defined limits.

Results

A DOE was performed to relate sealing performance to the force, dwell time and temperature profiles. For each trial, all of the temperature and force waveforms were recorded by the sigPOD, and stored to a QualityWorX database for post analysis. By analysing the data in QualityWorX, the customer was able to establish a correlation between the measured parameters and the seal performance. The algorithms developed in QualityWorX were then configured in the sigPOD to allow the sigPOD to determine seal pass/fail status in real-time, on the plant floor. By catching the defective packages while they were being sealed, the customer was able to dramatically increase their yields at the downstream destructive peel test. In addition, they were able to identify and address packaging issues early by monitoring the in-situ yields, instead of having to wait for the peel test results, by which point a large number of parts could have run through the underperforming sealer. The end results are significant cost savings due to the improved yields, while increasing test coverage and proof of compliance to 100%, ensuring that each and every device is safely sealed in a sterile package, ready for use.

Request more information: www.sciemetric.com
inquiries@sciemetric.com
1-877-931-9200

sciemetric