# Vial Seal Quality Insights: Seal Tightness Drone for Sealing Force Measurements

Seal quality is critical to vial container closure integrity assurance in parenteral filling and finishing processes; it's required in order to maintain microbiological integrity, sterility and physico-chemical attributes over the shelf-life duration of products (USP 1207).

Sealing of the vial with an elastomer closure takes place at the surface between the stopper flange and vial flange and seal quality is determined by the compression force at this interface.

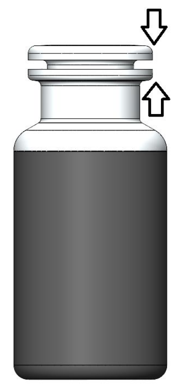


**Figure 1.** Seal Tightness drone with axial sensor integrated into flange.

> **SmartSkin has developed a novel sensing device (known as a 'drone') for measuring the forces applied to the flange of a vial within normal capping operations (Fig. 1).**

The Seal Tightness drone is shaped like a production vial and able to run with the vials at production speeds through capping and crimping processes.

It accepts a regular stopper and measures the force applied between the top and bottom of the flange, measuring the external top load force applied and the force applied by a metal crimp. This offers a unique look into the sealing forces applied during regular operations and facilitates further investigation into seal dynamics.

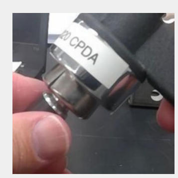
## Proof of Concept: MSD West Point, US

Proof of concept tests were done at the MSD West Point Lab, PA, USA (Fig. 2):

- 2 ml and 3 ml Seal Tightness drones were stoppered and capped.
- The drones were lifted into the jaws of a Kebby Pneumatic K-Head Capper for capping and crimping.
- After crimping, the drones were tested in a Genesis RSF Tester.
- A Kebby Decrimper was used to decrimp the drones after testing.

STM drone with stopper and cap.

Testing in the Genesis RSF Tester.





Decrimping with a Kebby Decrimper.

**Figure 2.** Proof of concept testing with a Kebby Pneumatic K-Head Capper, Genesis RSF Tester and Kebby Decrimper.

## Results

A large increase in top load force up to 220 N was seen at the start of capping followed by an immediate drop at the end of capping to below 100 N (relaxation of the seal and stopper).

An interesting observation was a drop of 10-20 N during button removal. Another drop was seen after RSF testing, presumably from the deformation of the seal and restressing the stopper (Fig. 3).

A correlation was found between the drone output when compared with the RSF Tester output and for vials under the same test conditions (Table 1).

**Table 1: Residual seal force measurements based on target capping force.**

| Target Capping Force (N) | 89.0 | 111.2 | 155.7 | 177.9 |
|---|---|---|---|---|
| RSF Tester Reading | | | | |
| Average for glass vials (n=5) | 43.1 | 50.1 | 52.0 | 54.1 |
| Reading for Drone | 51.2 | 53.8 | 48.9 | 74.7 |
| Seal Tightness Drone Results | | | | |
| After capping | 62.3 | 68.9 | 78.3 | 96.1 |
| After flip cap removal | 48.5 | 51.6 | 62.7 | 81.0 |
| After RSF Tester | 43.6 | 49.4 | 55.2 | 77.0 |

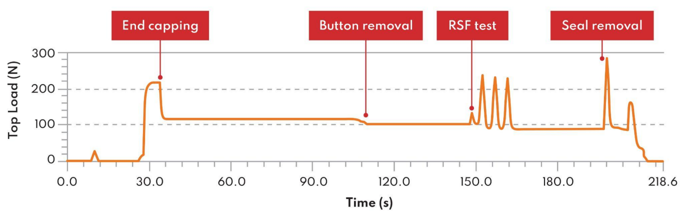



**Figure 3.** Example run timeline of the top load pressure (N) measured with the Seal Tightness drone through end capping, button removal, RSF testing and seal removal.

## Production Testing: GSK Wavre, BE

GSK completed in-production testing using a 2 ml Seal Tightness drone to check the performance of an 8-head capping turret. The same drone was passed through the machine 8 times to test each of the turret heads.

Results showed that the initial top load pressure applied by each head when applying the cap was very consistent (Fig. 4). Seal tightness, however, showed **unexpectedly high variability with a 10X difference between the lowest and highest value** (Table 2).

It was determined that the crimping wheels need adjustment to ensure that a sufficient seal force is being generated on every vial.

**Table 2: Initial top load pressure (N) and seal tightness (N) on capper turret heads measured with the Seal Tightness drone.**

| Turret Head | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|---|---|---|---|---|---|---|---|---|
| Initial top load pressure (N) | 215.7 | 215.7 | 210.8 | 207.9 | 213.8 | 223.6 | 205.0 | 207.9 |
| Seal Tightness (N) | 72.6 | 26.5 | 13.7 | 69.6 | 17.7 | 139.3 | 74.5 | 25.5 |

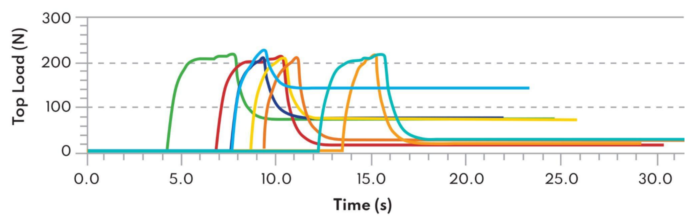



**Figure 4.** Top load pressure (N) and seal tightness (N) measured with the Seal Tightness drone through eight capping heads.

## Conclusion

The new Seal Tightness drone offers the ability to directly measure the sealing forces applied to vials through capping and crimping processes.

Possible applications for the device include the standardization of capper setup and monitoring of seal tightness over time under different environmental conditions.

MERCK gsk