Genesis Packaging Technologies

Vera

Residual Seal Force Tester

The Genesis Vera Residual Seal Force Tester evaluate's seal tightness by measuring the Residual Seal Force in the stopper/seal combination of a parenteral package created as a result of the vial sealing process.

Design Highlights

The Genesis Vera Residual Seal Force Tester measures residual seal forces on parenteral vials sealed with stoppers, lined seals and aluminum caps.

The aluminum caps can be plain aluminum, or aluminum with plastic buttons, though it is highly recommended that the plastic buttons be removed prior to testing. Other cap materials and styles may be accommodated as specialty applications. Specialty applications should be submitted to Genesis engineering for evaluation. Vials with diameters of 8mm to 88mm, and heights (including vial, stopper and cap) up to to 7.25 inches are accommodated. A wide variety of cap styles and sizes can be accommodated with specific cap anvils. Cap sizes including 7.5, 8, 10, 11, 13, 16.5, 17, 18, 20, 28, 30, 32, and 43 mm are supported. Residual seal forces in the range of 3 Lbf to 35 Lbf can be measured.

The residual seal force is measured by applying strain (compression) at a fixed rate to the cap/stopper/vial package and collecting strain (distance) vs. stress (force) data. This data is analyzed by a proprietary data analysis algorithm to determine the residual seal force.

The measured residual seal force is displayed on an operator interface on the front of the instrument and is automatically stored in a secure SQL database. The display includes a graph of captured data and analysis data points.

For research or validation purposes, data is exported to a secure SQL server which is accessible using the Microsoft Excel program provided. The data reporting includes secured raw data and multiple graphical templates for easy data analysis.

The instrument includes a safety enclosure to protect the operator in the unlikely event of glass breakage or slippage, and to keep fingers away from the actuator assembly during the process of collecting data.

All manuals and validation documents are provided digitally as PDF files as well as on board in a HTML 5 searchable format.

Genesis brings to the table much more than the time-honored Westcapper® sealing technology. We bring a complete understanding of the parenteral package itself. Our technical experts maintain long-standing relationships with parenteral package component manufacturers. We know the vial package. Our expertise in the science of sealing is deep-rooted and so is our commitment to seal integrity.

Design Highlights

Features

Modern System Controls

The control platform utilizes a reliable PLC for all data acquisition and resultant processing.

Modern Touch Screen Interface

The tester features a 10.1 inch touchscreen system.

Adjustable Vial Rest

The vial rest is adjustable to fit any vial size from 8mm to 88mm without having to change parts.

Dual SI & Imperial Units

Units for reporting can be switched between Imperial (Lbf Inches) and (Newtons mm). The selection becomes the default for future operation.

Graphical Data Display

The improved 10.1 inch screen allows for rich graphical data and reports to be displayed right on the tester.

Customizable Sample Labeling

The ability to add custom labels to your samples allows for more robust sample tracking.

Improved Accuracy

The Vera obtains several hundred force data points to allow for a more accurate analysis.

Improved Force Calibration

The force feedback entails a step by step process with a three point final verification and date/time stamp.

New Distance Calibration

A distance calibration process has been added and includes a three point final verification with date/time stamp.

Design Highlights

Features

Spreadsheet Data Export

The ability to export reports and graphs to a Microsoft Excel spreadsheet or Crystal Reports. A licensed copy of Excel is included with the unit.

Wireless Mouse & Keyboard Support

Wireless mouse and keyboard support is now built in to the embedded PC.

User Security Management

Manage users with fine grain security controls to restrict access and control use cases. Options are available to automatically obtain user credentials from a customer's secure server.

21 CFR Part 11 Capable

The Vera is capable to be 21 CFR part 11 compliant.

VHP Sterilization

The Vera has been certified for use with Vaporized Hydrogen Peroxide.

CE Compliant

The Vera has been certified to be CE compliant.

Specifications

Vial Finish Diameter	Vial Height	Power	Data Export	Size	Weight
8mm to 88mm	Up to 6.47 Inches	110/220 VAC	2 USB, 1 Ethernet	W: 13.7 [348mm] D: 18.4 [468mm] H: 29.3 [745mm]	112 Lbf [50.8Kg]

The Vera

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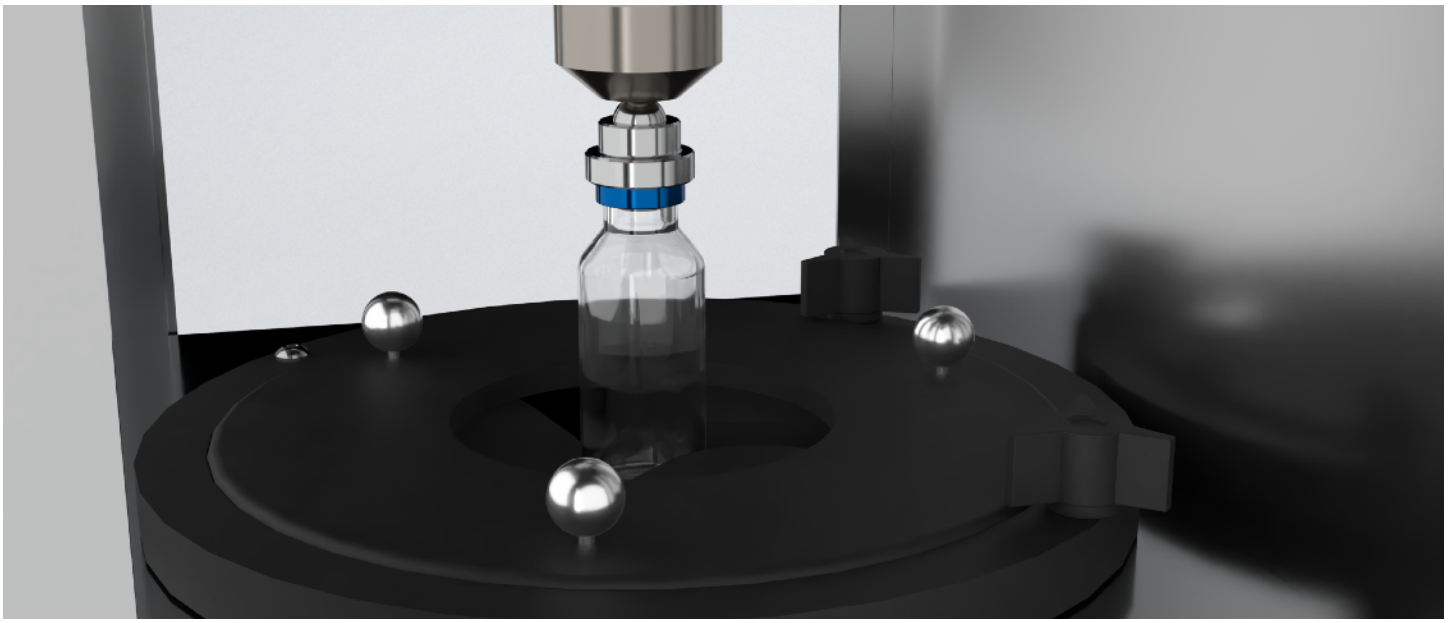

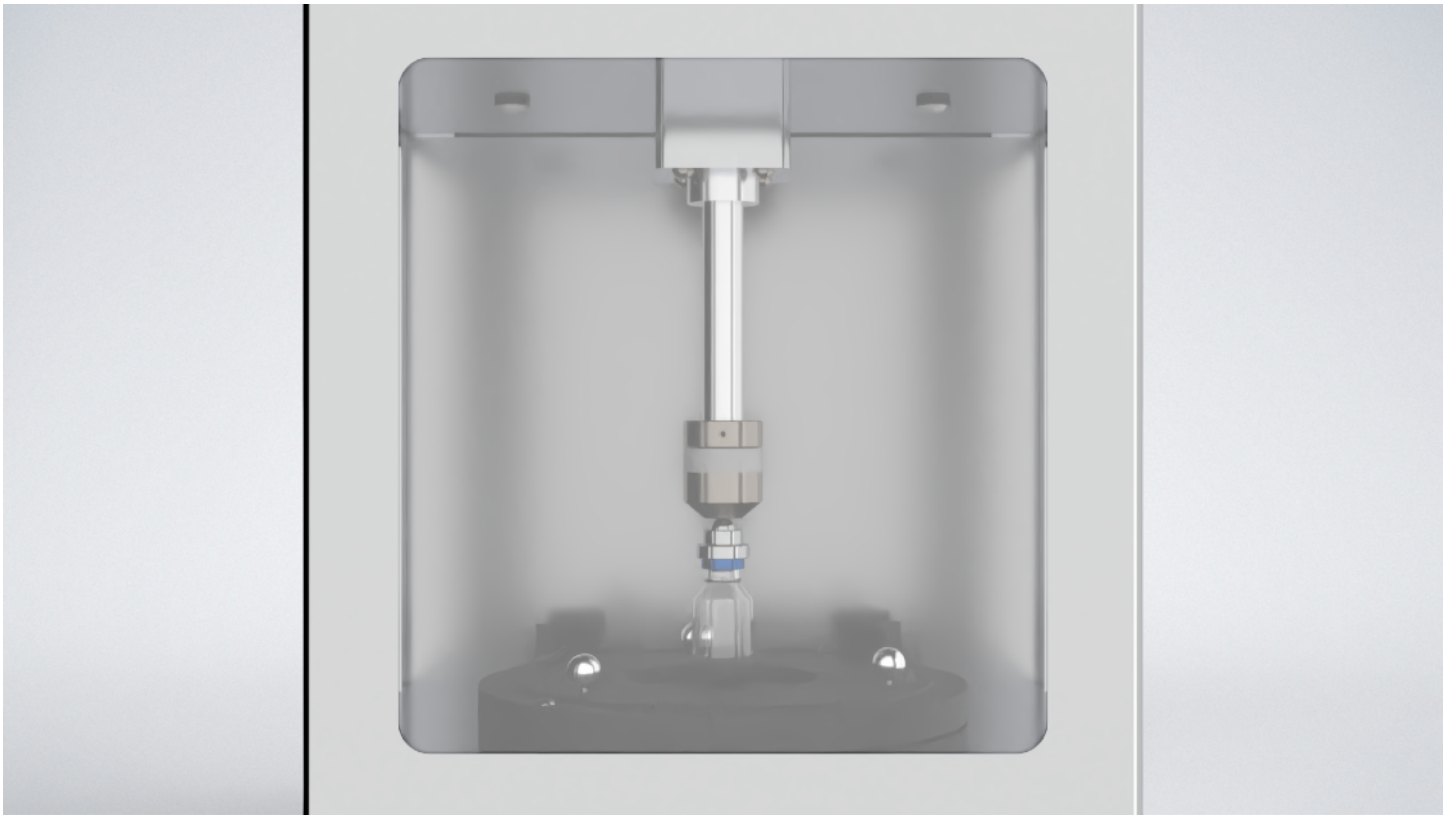

What is Residual Seal Force?

The force applied to deform the stopper creates a reciprocal force in the stopper. Once the applied force is released from the crimped stopper the reciprocal force created by the deformed elastomer becomes the Residual Seal Force (RSF) of the package.

Residual Seal Force, then, is the stress an elastomeric closure will continue to exert against the glass vial finish and the overseal after the capping operation is complete.

A parenteral vial system consists of a vial, a stopper and an overseal. Container/closure integrity of this parenteral vial system is achieved primarily by the proper deformation of the rubber stopper. Deformation is achieved by compressing the stopper against the sealing surface of the vial finish. Once compressed, the stopper is held in place by crimping an aluminum ferrule or seal around the components. In deforming the rubber stopper, the viscous flow of the elastomer fills and seals the voids between the sealing surfaces of the vial finish and the stopper flange. The elastomeric property of the rubber, which is the tendency of the elastomer to revert to its original shape while being held it in the deformed state, creates a force (strain) that effectively maintains the created seal. Although the compression of the stopper plug created by the interference fit between the plug and the inside diameter of the neck of the vial may also create a seal, it is the vertical force from the compression of the stopper flange against the top of the vial finish that creates the primary and more reliable seal. By correlating RSF to stopper compression and CCI testing during packaging development RSF may be used as a predictor of container closure seal integrity (Orosz, Guazzo 2010)*. This work clearly shows that an appropriate amount of stopper compression creates effective container closure integrity where leak rates of less than 10-7 Pa m3/s can be achieved even on glass vials with "large" surface defects. Therefore, the primary function of a sealing operation is the deformation of the rubber stopper by compression; secondary is the crimping mechanism to hold that compressed stopper in place.

It is important to understand that Residual Seal Force is not a constant value. The change in RSF can be illustrated graphically utilizing the degenerative Maxwell Curve. Changes in RSF are the result of stress relaxation and the compression set of the elastomer. Over time, as indicated by the curve, the elastomeric stress continues to very slowly decline due to the rheological characteristics of the rubber until a relative plateau is reached. A specific RSF value is meaningless unless its location on the curve is known since the changes in stress are not linear. This degeneration and its effects on RSF need to be understood for each elastomeric formulation and stopper design. The physical and mechanical properties of the closure are determined by the rubber formulation and the stopper dimensions. These properties include durometer (relative hardness), compression set and modulus of elongation. Thus the stress relaxation curve and residual seal force may vary with each different rubber formulation. Processing and storage parameters, particularly temperature, may also influence this curve. By correlating RSF values with the compression of the rubber stopper and the corresponding leak rates, the measurement of RSF can be used to effectively evaluate proper and continued sealing of the vial system. FDA in its Guidance for Industry Container and Closure System Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products recognizes the usefulness of properly validated seal force testing. Most importantly, RSF is useful in the establishment, validation and control of capping machine settings.

*Orosz and D Guazzo, "Leak Detection and Product Risk Assessment' presented at PDA Meeting, Mar 2010, Orlando, FL

Stopper Compression Analysis

The Stopper Compression Analysis Service Provides Critical Information Necessary to Insure Robust Seal Integrity and Repeatable Capper Setup

A stoppered vial is a universal parenteral drug container closure system. The system however, should not be considered integral until the rubber stopper is crimped firmly in place with sufficient compression against the vial finish assuring all potential leakage is cut off at the seal interface. Analysis of this seal integrity should be a critical aspect of the packaging development, evaluation and qualification.

A parenteral vial container closure system is made integral by compressing the flange of a rubber stopper against the sealing surface of a vial (finish crown) and securing it in place with a crimped aluminum ferrule or seal. The elastomeric properties of the rubber maintain a force that effectively seals the vial. Our experienced technicians analyze your specific container closure system and determine the optimal compression percentage to achieve leak rate cut off. This value is then correlated to Residual Seal Force (RSF) and verified by a standard leak testing method.

The RSF value is the measured stress the compressed rubber closure flange continues to exert on the vial-sealing surface after application (crimping) of an aluminum ferrule. By correlating RSF values for each set of vials to the compression calculation for those vials, RSF can then be used as an indirect test method to estimate closely the elastomeric closure compression.

RSF values may be used in effectively setting up vial cappers and for monitoring the crimping process. With an understanding of compression and leak rate cut-off RSF can be further used as a predictor of leakage risk.

Genesis provides a complete report which includes all the test procedures used and data collected. This information can then be used to develop your vial sealing SOP's.

The report includes:

1. Stopper Flange Compression Analysis
2. Levels of Compression Graphics
3. Compression and Residual Seal Force Data
4. Residual Seal Force Measurements
5. Helium Leak Testing
6. Discussion and Recommendations
7. Stopper Compression Measurement Procedure
8. Residual Seal Force Measurement Procedure
9. Package Component Specifications

Vial Optimization

The onsite vial optimization procedure carried out by Genesis is a means by which capping machine parameters are obtained through a careful process of studying component structure, variation and stopper compression analysis.

Optimizing for Container Closure Integrity

Machine settings are considered optimal when optimum stopper compression has been achieved. Genesis bases its optimal compression standards on research and experience. Where feasible, a quality, aesthetic package appearance is also obtained.

It is extremely important to understand, and it should be noted, that the optimized machine settings are directly related to the components being processed during the optimization procedure. If any one component i.e. overseal, stopper or vial, is changed, the machine parameters are no longer applicable and new studies need to be carried out.

The following tasks are carried out during the optimization procedure:

1. Precise package measurements.
2. Stopper compression analysis based on package measurements.
3. Vials processed below optimal compression (spring related).
4. Vials processed above optimal compression (spring related).
5. Vials processed at optimal compression (spring related).
6. Residual Seal Force studies of vials processed at all levels of compression.
7. If requested by the customer, leak testing of randomly selected vials from each compression group can be provided.
8. Sealing Rail Setup (performed only at optimal compression and head height settings)
9. Head Height Setup (performed only at optimal compression and rail settings)

How Can We Help?

Genesis provides technical consultation and training in all areas of parenteral packaging including: the selection and utilization of container/closure components, materials of construction, packaging development, risk assessments, supplier qualification, container/closure integrity, regulatory compliance and investigations.

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Parenteral pharmaceutical packaging is the core of our work. It's scope includes the traditional vials with elastomeric stoppers, cartridges and pre-filled syringe systems, and in developing novel and innovative components, and drug delivery systems, including combination products. We have extensive experience with the customary materials of glass, rubber and metals, but also with the advanced plastics and laminate materials being promoted today.

We are knowledgeable of the regulatory requirements and guidances concerning the packaging of pharmaceuticals and container closure systems and have experience with US and worldwide authorities. Our consultants are professionals serving on various technical committees and interest groups of organizations such as PDA, ISPE, ISO and ASTM. They are teachers, sharing their knowledge at seminars and training sessions around the world.

Some of the things we do:

1. Container/Closure System Development
2. Product/Process Improvements
3. Container/Closure system Evaluation and Qualification
4. Supplier Management
5. Training and Education
6. Vial Optimization

Service Packages

Small Machine Packages

Service and training packages for the Integra Laboratory Crimper and the Vera Residual Seal Force Tester. Discounts are available for purchase of multi-year or combination (service & training) packages.

Select Service
Annual Billing

- ✓ Includes one visit annually plus all travel and living expenses.
- ✓ Preferred scheduling.
- ✓ Up to 4 hours of telephone or virtual tech support annually with anyadditional hours billed in ¼ hour minimum increments.

Premium Service
Annual Billing

- ✓ Includes two visits annually plus all travel and living expenses.
- ✓ Priority scheduling.
- ✓ Up to 8 hours of telephone or virtual tech support annually with any additional hours billed in ¼ hour minimum increments.

Select Training
Annual Billing

- ✓ Includes one on-site training session annually for up to 4 operators plus all travel and living expenses.
- ✓ Preferred scheduling.
- ✓ Up to 4 hours of telephone or virtual training support with any additional hours billed in ¼ hour minimum increments.

Premium Training
Annual Billing

- ✓ Includes two visits annually plus all travel and living expenses.
- ✓ Priority scheduling.
- ✓ Up to 8 hours of telephone or virtual tech support annually with any additional hours billed in ¼ hour minimum increments.

www.gen-techno.com

Genesis Packaging Technologies is a Worldwide Leader in the Science and Technology of Parenteral Vial Sealing and Residual Seal Force Testing

We provide advanced vial sealing equipment for the packaging of critical injectable pharmaceutical products. Genesis designs, develops and builds vial cappers with innovative technologies that meet the technical challenges of parenteral pharmaceutical packaging, assuring seal integrity in compliance with advancing regulatory requirements for aseptic processing and container closure integrity. Offering our customers the tools and knowledge to consistently achieve container closure integrity remains our priority.

Purchasing equipment from Genesis provides customers support from a company with over 75 years of experience dealing specifically with vial handling equipment and technologies. Service is available on all equipment manufactured by Genesis and the former Machinery Systems Division of The West Company.

For the better part of a century Genesis Packaging Technologies has been at the forefront of sealing technology. Providing the pharmaceutical industry with parenteral vial sealing solutions is what we do.

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