TechNotes

Getting the most up-to-date information on materials testing





Explore. Engage. Educate.

Tell us more about your interests and you'll start to receive relevant articles and updates in your email.



Dear Readers,

A few of the many things we learned in 2015 is that businesses around the globe are faced with the challenges of increasing efficiencies by doing more with less and increasing throughput by utilizing new technologies, allowing customers to work smarter. Whether you are the manager of a quality control lab or an engineer in an R&D lab, the demands to grow your business are constant. We remain dedicated to helping customers meet these demands by keeping the customer at the core of our culture.

This third annual TechNotes: Year in Review is a compilation of what we developed throughout 2015. We remained focused on solutions to customer challenges through the development of new products that meet the demands of doing more with less; we strived to improve the customer experience through the release of a new website and the introduction of a strain microsite; and we shared our experts' knowledge on new technologies and ways to work smarter through live webinars, focused newsletters, and industry articles.

Another way to easily connect with our experts is through LinkedIn, Twitter, and Facebook. And you can easily follow us on YouTube and Slideshare for the latest videos and informative presentations. It's easy to join the Instron Community and stay current with our application solutions.

Thank you for your continued interest in our communications.

Best regards,

Denise Czerpak

TechNotes Editor

CONTENTS

- 04 The Customer Report:Achieving Strategic Solutions
- 06 Article: Why Automate Your Materials Testing
- 10 New Program: Lab Health Check
- 11 Industry Insights: Thought-Provoking Articles from the Experts
- 12 Article: Non-Contacting Extensometry Excels in Strain Measurement
- 15 New Program: Trade Up Program
- 17 Webinars: Live with Instron Experts
- 18 Article: Maintaining High Standards for Medical Packaging
- 22 Trends in Technology: Newsletters
- 24 Community Connections: Making a Difference In Our Area



Wentworth Institute of Technology

CUSTOMERS ACHIEVING STRATEGIC SOLUTIONS



In the Boston, MA area, there are many prestigious technical colleges and universities that blanket the city and surrounding areas. One of these colleges is making sure that their students receive a high level of hands-on learning to better prepare them for the real world and position them for entry into a competitive job market.

The Challenge

Wentworth Institute of Technology students are no stranger to basic testing equipment using manual calculations when it came to materials testing; however, some of testing equipment in their facility were dated back to the 1950s. The systems could perform general tensile tests, but lacked modern features. As an institute that focuses on practical engineering and not theoretical engineering, they realized their existing lab put the curriculum and students at a disadvantage.

"Our core values center around our students, enabling them to experience hands-on learning, and to place innovation and creativity at the center of what we do," says Mike Jackson, Department Chair of Mechanical Engineering & Technology. "How could we do that with equipment that has been around since the 1950s and 1960s?"

Wentworth had a vision to transform their lab into an advanced learning environment with the latest and most innovative technologies available. This was necessary to equip their students with an experience level that would allow them to compete with – or exceed the practical engineering experiences of their peers.

The Solution

Jackson and his colleagues looked not only at what their students needed for basic strength of materials research, but decided it was equally important to focus on the training and experience students would benefit from in order to progress into a Master's program. This forward-thinking approach opened the door to more advanced techniques and concepts than what was originally offered.

"After discussions about what we needed and where we wanted to go, it was really an easy decision," said Jackson. "One thing that sold us on Instron is that all of the equipment uses the same Bluehill® Software – whether it is an Instron system or our additional non-Instron system, which still used a dial indicator, also benefited with an upgrade to match the latest Instron technology. This removes the learning curve not only for our faculty and technicians, but also for our students because each student receives their own laptop that can be connected directly to a machine."

Funded in part by a \$1 million gift from the Gelfand Family Charitable Trust, WIT grew from a once crowded and outdated lab to a modern basic strengths and an advanced strengths lab that is equipped with 11 new Instron systems for testing tension and compression, torsion, metal and plastic impact, and fatigue. Ranging from 5900 systems



to torsion systems, there is also an environmental chamber and a non-contacting extensometer with video capability, allowing students to have instant verification of their calculation using the new computer controlled equipment.

Together with the Instron Service team, the facility and staff were able to get the equipment and the new Gelfand Strength Lab configured properly in order for the academic team to immediately go to work using the new machines.

Each piece of equipment is connected to a computer with Bluehill Software, allowing students to capture, plot, and analyze data without having to manually examine each data point. The students time in the lab is maximized and, more and more, discussions are focused on outcomes—on the how and why. Each lab includes classroom space that allows the students and faculty to easily move back and forth from theory to hands-on application.

The Results

Far exceeding all expectations, the students are enjoying the new facility and systems, working on projects that only two years ago weren't possible. The equipment enables students to explore advanced topics that in the past were noted during lecture but never tested. The labs also provide wonderful opportunities for applied research at the undergraduate or graduate level.

The Gelfand Strength Lab is a cornerstone of the university and is attracting students that may not have previously considered WIT. Graduating students are now equipped with a mechanical engineering education that hosts the ability to use the most advanced materials testing equipment and experiences based on the most current technologies available.

This new lab allows us to advertise ourselves as a truly modern engineering school...

"This new lab allows us to advertise ourselves as a truly modern engineering school, while allowing us to keep our historical hands-on approach," said Jackson. "There's not too much we can't do. Once our students graduate from our program, they can go anywhere."

READ MORE ABOUT OTHER CUSTOMER JOURNEYS



To adhere to the proper ASTM and ISO standards required for their industry, Naton Medical Group needed a solution that guaranteed their results and reduced the amount of product discarded during testing.

Read more about their journey.



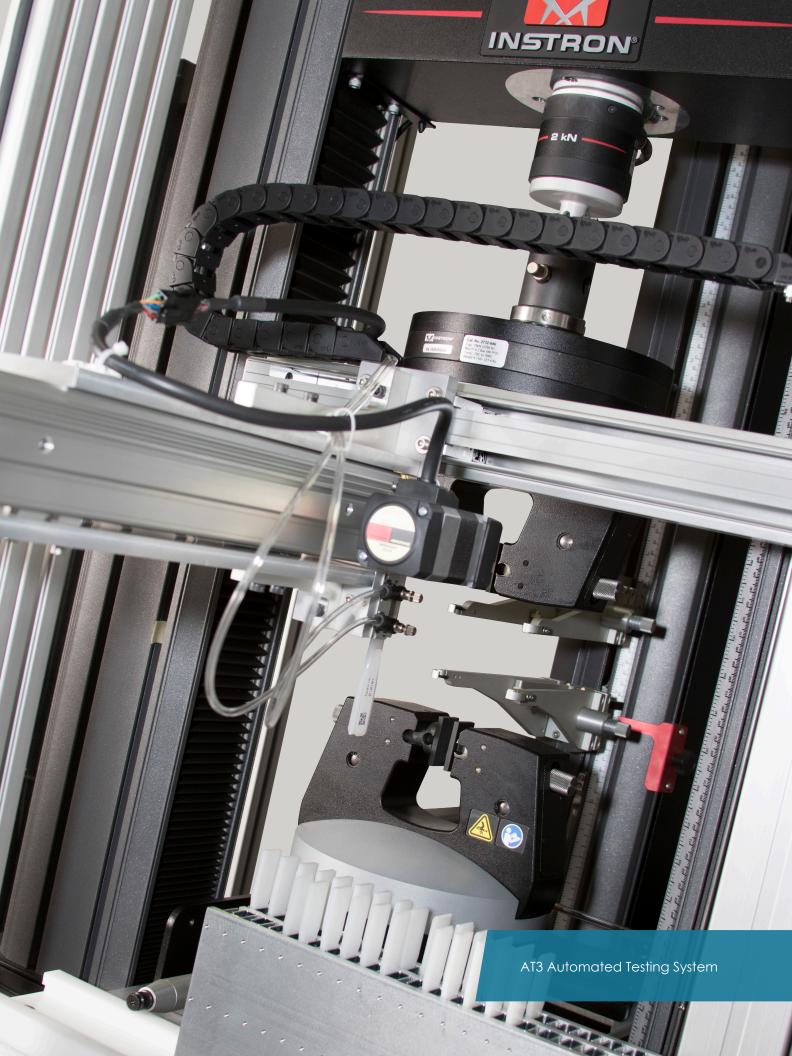
Driven by the need to perform excellent research to develop new test methodologies specifically for thermoplastic composites, TPRC began to research equipment that matched the type of testing they were performing: state of the art.

See the outcome.



Synoste's philosophy of patient friendliness, usability, and device reliability has driven them to develop a less painful and precisely controllable treatment device that lowers the complication rate and enables faster recovery to normal life.

See what their research showed them.





WHY AUTOMATE YOUR MATERIALS TESTING

Suzanne Delemos-Williams, Senior Applications Engineer

Automation is all around us. Without even realizing it, we often use automation in our everyday lives: the automatic doors at many stores; automatic car door windows; ticket booths and toll booths; electronic devices; even on-line banking – all commonplace forms of automation that help us out in our everyday lives.

So why are we so resistant to use automation to help in our mechanical testing? The stigma around automation in a lab is that the system is too:

- Expensive management will never fund it
- Complicated training costs will be too high, our operators won't like it
- Inflexible what if our testing requirements change over time; we'll be stuck with equipment we can't use

However, automation is the way of the future. It removes human element from testing, reducing re-testing due to data entry errors and failed tests, resulting in quicker go/no go decisions for the end customer (a decision that could be holding up an expensive shipment – meaning loss of revenue). Automation offers a better use of skilled labor. Instead of spending their time loading a testing machine or waiting for a test to end, operators can work on more value-added tasks. Companies will see an increase in testing efficiency because automation allows testing laboratories to keep up with increased testing demands without having to add personnel, as automation can run over night and on weekends

companies will see an increase in testing efficiency

unattended; ultimately increasing lab throughput. Lastly, automation improves the safety of personnel, reducing repetitive motion injuries, and keeping operators clear of testing equipment and moving machinery.

If we look at a typical testing cycle there are many manual

(and tedious) steps involved.

A typical testing cycle can look like this:

- 1. An operator enters a batch or specimen ID
- 2. The specimen is often measured, usually in three places
- 3. The specimen information is manually entered into the software
- 4. The operator loads the specimen into the grips
- 5. If needed, an extensometer is attached to the specimen
- 6. The operator initiates the test
- 7. The operator needs to wait for a test to complete
- 8. The tested specimen is then removed from the grips
- The operator must manually transfer the results to the database

All of these steps take valuable operator time and many have the potential to introduce errors and variability that could create more work by having to re-test specimens.

Performing manual measurements is time consuming and cumbersome with many opportunities during the measurement to either write down or enter misinformation. Numbers can be written down wrong, transposed, or forgotten. At times, testing labs experience the measurement process taking up a third of their testing process time.

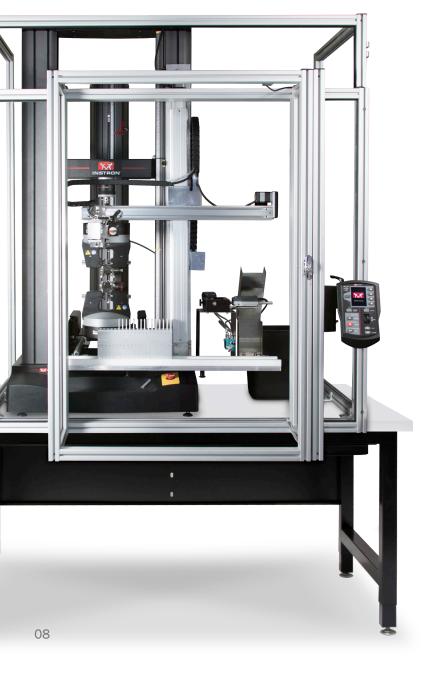
Loading specimens into testing equipment is highly operator dependent and can have a big impact on your results. Specimens can easily be loaded incorrectly: too high or too low, off-center, or at an angle.

An example of this could be two operators testing the same batch of specimens. Operator A tends to test on the high side. While most of the testing stays within the product limits, occasionally results are out of range creating a situation where good product is not shipped. Operator B, on the other hand, tends to test on the low



side. Again, most of the values stay within product limits but occasionally, due to lower limit testing, some product that should actually be rejected, unfortunately passes and results in bad product being shipped. It all comes down to the operator's technique and the difference between operators could be a detrimental cost the company.

One of the final steps in the testing process, and probably the most crucial, is often the transfer of testing results into a LIMS or master database so that results can be analyzed, tracked, and used to make important product decisions. Similar to manual entry of the information at the beginning of the testing process, manual entry of results is time consuming and increases variability and errors.



The Automation Continuum

No matter what your testing requirements or budget constraints are, there is always an incremental, automated solution that can offer various levels of benefits without having to necessarily go to a full robotic testing system. This is called the "automation continuum".

The automation continuum offers phases of automation and allows a lab to automate parts of their testing process, usually starting with their greatest pain point.

Take data entry, for instance. By adding barcode labeling and a barcode reader, all the necessary batch and sample information can be loaded into a testing system or LIMS by simply scanning a barcode.

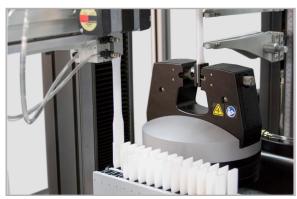
Not only does this simple addition to the testing process decrease variability, it frees up valuable operator time to perform other tasks and it requires no special training to learn how to scan a barcode.

Another pain point that can be easily automated is specimen measurement. Automating measurements can be as simple as changing from a manual micrometer to a digital micrometer on a stand. An operator loads the specimen into the micrometer mounted on a stand and by pressing the red upload button on the micrometer, the measurement value is automatically loaded into the testing software.

If further automation is desired, an automated measurement device that can measure width and thickness at the same time can be introduced. With this solution, an operator loads the specimen into a device that measures both width and thickness, and then automatically loads these values into the testing software. If multiple measurements are desired, the automatic device can store the separate values and then transfer the desired measurement value (average, max or min) into the testing software. This saves valuable operator time and reduces variability.

The second of th

AT3 Specimen Scanning



AT3 Specimen Holder

As we move along the typical testing sequence, the next step in the process is extensometer attachment. This can be very time consuming and it requires a lot of skill and concentration to attach properly. By adding an automatic extensometer into your testing system, setup time is reduced due to the automatic extensometer automatically sets to the desired gauge length. Results variability is decreased, as the extensometer automatically attaches properly to the specimen and in the same location for every sample. Lastly, using an automatic extensometer improves operator safety and ergonomics by allowing the operator to spend less time in the testing area and alleviating body fatigue due to not having to mount and position a clip-on extensometer.

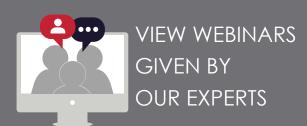
WANT TO LEARN MORE?

WATCH A VIDEO



The Benefits of Automated Materials Testing WATCH NOW

Test 80 Specimens Per Run With Fully Automated Instron TestMaster AT3 WATCH NOW



Automation - The Next Level Of Productivity & Consistency

- Lorenzo Majno & Suzanne Delemos-Williams
WATCH NOW

New Economical Fully-Automated Testing Systems

- Lorenzo Majno & Suzanne Delemos-Williams
WATCH NOW





HOW CAN INSTRON HELP YOU TO PLAN FOR THE FUTURE OF YOUR LABORATORY?

The pace of technology has never moved faster than it does today. All businesses across every industry face an increasing challenge in ensuring they have a long-term plan to deliver business continuity to their customers and to cope with the pressures of obsolescence. Building a strong upgrade strategy for materials testing equipment can be challenging as it often relies on a combination of mechanical parts, electronics, and testing software. Instron recognizes the important role that we play in working with our customers to move their laboratory equipment onto modern technology platforms and in building a long-term laboratory obsolescence strategy.

Our new site survey tool helps you to understand the state of your existing laboratory equipment. In just a few hours we carry out a full survey of all of your materials testing equipment. Through the use of modern technology we have been able to make this process quick and easy while delivering you an easy-to-understand and insightful report that will highlight machines at risk, as well as the biggest opportunities for modernization and enhancements.

If you have struggled to obtain funding in the past for upgrading equipment or have never tried, this report will help you to build a strong business case for investing in your lab. There are a wide range of solutions available from a simple pc and software upgrade, through to new tools that will increase machine utilization.

*The Lab Health Check may not apply to all locations - consult your local Instron Sales for details.



WATCH THE VIDEO TO LEARN MORE

INSIGHTS. INDUSTRY. INSPIRE.

Our experts are speaking out to share with you the latest industry insights, delivering first-hand knowledge directly to AZoM readers.



The MPX Series of Motorized Pendulum Impact Testers
An Interview with Matt Spiret
Read More

The Three Main Challenges in Plastics Testing

An Interview with Rich Goshgarian

Read More





The Challenges in Rebar Testing
An Interview with Tom Wodcke
Read More

Building a Business Case for Modernisation
An Interview with Nick Shrubsall
Read More



OTHER THOUGHT-PROVOKING ARTICLES FROM INSTRON EXPERTS

A Reputation Built on Innovation

- Tom Davies Featured in European Business Journa

Women in Plastics

- Elena Mangano

Featured in British Plactice and Pubbars

She's an Engineer

- Maeve Higham

Featured in Women's Engineering Society

Steel Reinforcement Bar: A Tensile Testing Guide

- Jeff Shaffer Featured in AM&P Magazine



NON-CONTACING EXTENSOMETRY EXCELS IN STRAIN MEASUREMENT

Elena Mangano, Assistant Product Manager

Stress and strain are the two fundamental components of a materials test. When a material is put under a compressive or tensile load, stress is the load relative to the cross-sectional area of the material, while strain refers to how much it elongates. Both stress and strain data provide important material characteristics such as stiffness, yield stress or yield point, ultimate tensile strength, and total elongation. Many industries require use of calibrated and verified equipment to measure a material's stress and strain—usually with a universal testing machine, load cell, and an integrated extensometer or strain measurement device.

strain data must be of the highest accuracy and repeatability

Various extensometers are commercially available for a wide range of materials and provide accurate strain data for specific applications. Often this strain data must be of the highest accuracy and repeatability, as many critical material characteristics depend on accurate, early-in-test strain data. The resulting characteristics can be used as quality control benchmarks, and/or material selection criteria in research and development with great impact on the final components.

Testing Standards

Most industries, such as polymer, steel, and carbon fiber composite manufacturing, have regulated procedures for testing raw materials before they can be sold. These processes are most commonly governed by organizations such as the International Organization for Standardization (ISO), Geneva, and ASTM International, West Conshohocken, Pa. Other standards organizations exist globally and typically make small adaptations to the most common ISO and ASTM standards. Testing standards vary in stringency, some requiring very low accuracy instrumentation and some requiring high accuracy, high-resolution instrumentation to characterize materials. The stringency usually correlates with the material's end use. Composites, metals, and polymer manufacturing tend to have the strictest extensometry requirements within the materials testing sector due to the material's stiffness and use in critical applications.



Extensometers: Basics and Benefits

Extensometry can be contacting or non-contacting. As their names suggest, contacting extensometers require contact with the specimen, where as non-contacting extensometers use technologies like video or lasers to measure elongation. Non-contacting extensometry offers a wide range of benefits in materials tests. Depending on the specific application, non-contacting extensometry may be the only option for strain measurement.

NON-CONTACTING: The most obvious feature of non-contacting extensometry is that it does not come in contact with the specimen during tests. This is important for delicate materials, such as biomedical tissues, paper, and even some polymers. For some fragile materials, contacting extensometry can affect important strain-based calculations like modulus or yield. Heavy contacting devices can damage fragile specimens causing them to bend and deform during the test, and/or can dig into the material's surface with sharp edges, causing weakening at contact points and thus premature failure.

HIGH ACCURACY: Both BS EN ISO 6892-2:2011 and BS EN ISO 527-1:2012—the two most common global tensile testing standards—require very accurate extensometry (ISO 9513:1999 Class 1).

Non-contacting extensometer technology uses a combination of lighting, fans, and high-resolution digital cameras to achieve the accuracy needed for these applications, and can also perform advanced applications such as strain control and dynamic testing.

FLEXIBILITY OF APPLICATIONS: One of the most beneficial features of non-contacting extensometry is its ability to be used for almost any application. This flexibility allows adaptation to various tests with minimal changes to base equipment. Equally, non-contacting extensometers work well in quality control environments where repeatability and robustness are key.

VARIOUS LENSES: Most video and laser extensometers have interchangeable lenses. The different lenses dictate the field of view of the strain measurement—how much of the test space can be seen by the camera. Smaller field-of-view lenses are typically used when very high-accuracy measurements are required, such as in metals and composites tests, whereas larger field-of-view lenses are used for high-elongation tests, such as films and elastomers.

WANT TO LEARN MORE?

WATCH A VIDEO



A Revolution in Strain Measurement: The AVE 2 Non-Contacting Video Extensometer WATCH NOW

READ ARTICLES WRITTEN BY OUR EXPERTS

Taking the Strain

- Ian McEnteggart

Featured in Aerospace Manufacturing

Why Measure Strain Optically?

- Leo Martinez

Featured in Quality Magazine

Strain Measurement: Techniques for Composites Coupon Testing

- Ian McEnteggart

Featured in Quality Magazine

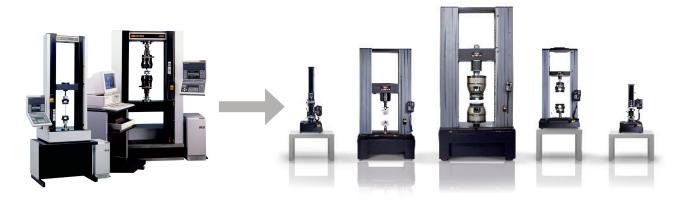


The installation and 1-day onsite training were excellent.

The service engineer went above and beyond to provide the training HART personnel needed, as well as to provide specific examples of test methods HART was initially applying.

- Christopher Schleigh, Senior Quality Engineer, Harvard Apparatus Regenerative Technology

TRADE UP PROGRAM



As technology continues to advance, we take pride in properly communicating any product life cycle changes. As a result, we have been reaching out to customers who may be affected by outdated equipment. We have recently contacted those who own 3300 Series Electromechanical System TouchPanel Controllers and 4500 Series Electromechanical Systems. We highly recommend trading up to new technology, although not mandated, to maintain and increase current testing performance.

^{*}The Trade Up Program may not apply to all locations - consult your local Instron Sales for details.

About Strain Measurement



STRAIN (ε)

Change per unit length in linear dimension, usually expressed as a percentage.

LEARN MORE



WATCH LIVE WEBINARS HOSTED BY OUR LEADING EXPERTS



THE FUNDAMENTALS OF RHEOLOGY TESTING With Ilaria Di Rienzo Watch Now



THE CHALLENGES OF REBAR TESTING With Jeff Shaffer Watch Now



HOW TO EFFICIENTLY SEARCH, ANALYZE & SHARE TEST DATA With Parasar Kodati Watch Now



PRODUCT LIFE CYCLE SUPPORT: 4500 SERIES ELECTROMECHANICAL TESTING SYSTEMS With Frank Lio

Watch Now



THE 3 CHALLENGES
IN PLASTICS TESTING IMPACT, MELT FLOW,
& HDT
With Shalmalee Vaidya

Watch Now







MAINTAINING HIGH STANDARDS FOR MEDICAL PACKAGING

Elayne Gordonov, Assistant Market Manager

The integrity of medical packaging is often evaluated with equal attention and rigor as the medical device itself, and should not be considered secondary to the device when it comes to qualification testing. Ultimately, the packaging is a vessel for the drug, device, or product, and needs to contain and protect what is inside.

With an aging and growing global population, emerging markets around the world, and the constant international pressure to reduce healthcare budgets, medical packaging is an area that needs to maintain high standards for quality testing, as well as having the potential for continued design innovation.

medical packaging is an area that needs to maintain high standards for quality testing

To address these challenges, and opportunities, it's crucial that testing of physical material characterization is conducted with best practices to adhere to international standards; that packaging design is done with the clinician, patient, or other end user in mind; and that data and records management is organized and well maintained to quality standards of the Federal Drug Administration (FDA).

Material Characterization

When many consider what encompasses quality assurance (QA) testing of medical packaging, often times mechanical testing is an obvious and non-negotiable component. For instance, when a manufacturer designs packaging for its medical device, the package integrity is key for keeping what's inside of the package sterile.

However, it's equally important that the package is easy to open by the end user, or else it could hinder the intended efforts. Because of this, one of the most common and effective medical packaging standards is ASTM F88-09 for determining the seal strength of flexible barrier packaging.

Measuring seal strength allows packaging labs to obtain quantitative measurements about their packaging

process. Often labs report the average force to open the seal and peak load during a test. For this test, it's critical to set the test speed at an appropriate rate and to ensure the universal testing machine has a high enough bandwidth to pick up the quick peaks and drops in loads during the peel. Many labs test their medical packaging not only to obtain relevant force data to open the package, but also to measure the consistency of the packaging process and other factors that could affect the strength of the package seal, such as a sterilization process or shelf time.

In addition to tracking seal strength of a package, many packaging labs also report tensile strength results of the bulk package material. While the package seal is the intended opening location, that's not always the case. Many consumers tend to poke and puncture the packaging to get a product out. Furthermore, packaging manufacturers need to avoid unintentional package damage caused in shipping, handling, or storage of a product.

For these reasons, medical packaging labs also test to ASTM D882-12 for determining tensile properties of thin plastic sheeting, which is often what flexible packaging consists of. Properties, such as tensile modulus, load at break, and tensile energy at break, are all used to characterize material properties best suited for housing a medical device.

While the same universal testing machine can be used to test seal strength and to test to ASTM D882-12, the tensile test is much faster than the seal strength test, so it's critical for packaging labs to set the data acquisition of their machines accordingly. If the data acquisition rate is set too low, generally above 100 ms, often tensile modulus results will be calculated from too few data points, resulting in poor stiffness data.

As mentioned, many medical devices are sealed into their sterile packaging in a cleanroom and loaded into protective packaging, or shipping cartons, for transportation.

This helps to ensure that the product is supplied to the customer in a sterile state. The transit simulation is carried out on populated shipping cartons, normally with two goals in mind: (1) to assess the performance of the shipping carton and its robustness in transport,



and (2) to subject the shipping carton's contents to the rigors of transport (this is more important for the medical device manufacturer). This allows performance testing of the sterile barrier packaging and assessment of the product. A typical example is the concentrated impact test, which simulates the effect of direct shock impact on a package by a concentrated external force, such as when packages collide.

ASTM D6344-09 is intended to evaluate the ability of packaging to resist the force of concentrated impacts from outside sources, such as those encountered in various modes of transportation. This test method determines the ability of packaging to protect contents from such impacts and to evaluate if there is sufficient clearance and/or support between the package itself and its contents. It's conducted using a free-fall tup (or striker) to test completely filled transport packages for resistance against concentrated low-level impacts, typical of those encountered in the distribution environment. The test result is a pass/fail determination and a record of the energy dissipated by the filled transport package during a low-level concentrated impact.

N. Merhour SDA2

Usability Testing

Quality testing for packaging is often conducted to abide by ASTM or ISO standards for material characterization. but also can focus on usability testing, especially the pharmaceutical Pharmaceutical industry. packaging has seen many changes in the last decade, especially in the United States with the aging baby boomer population and with more consumers requiring easy-to-use packaging for self-medication.

At many pharmaceutical companies, medical packaging is not just about flexible packaging, but also

includes rigid plastic or glass bottles, droppers, and syringes.

Standards exist for testing packaging to ensure batch-to-batch package variation remains low and to provide data on the product's usability.

ISO 7886-1 sets guidelines for sterile hypodermic single-use syringes for manual use, and specifies the test conditions for aspiration and ejection of liquids. The purpose of the test is to ensure that the forces necessary to move the syringe plunger and eject the fluid from the barrel are not too high or too low. Parameters that affect the amount of force to eject a drug could be the syringe material, viscosity of the liquid, the sterilization process, and geometry of the syringe. In addition to this, the age and gender of the host tissue could also affect the forces required to eject the drug.

When performing QA usability testing on syringes, packaging labs need to focus on the force required to move the plunger (known as the break-away force), as well as the friction of the plunger as it moves through the shaft of the syringe (known as the glide force).

Similarly, in 2014, ASTM Committee D10 on packaging developed ASTM D7860-14, a method for determining torque retention for child-resistant and non-childresistant packages with continuous thread closures, which can be specifically applied to medicine bottles. Child-resistant medicine packaging is needed to reduce the risk of children ingesting dangerous amounts of medication. However, making packaging too difficult to open by requiring too much force to push down and too much torque to twist may prevent elderly individuals with arthritis or disabled individuals from taking their needed medications.

In addition to safety concerns with opening the packaging, there are also concerns with the packaging of medicine bottles being too difficult to close. Capped medicine bottles that are stored incorrectly—ones that require too much torque to fully close—could lead to a change in dose concentrations of the medicine and cause harmful effects to the consumer. This type of mechanical testing for quality control purposes of medical packaging is not only useful to ensure a uniform manufacturing process, but also to ensure the product has been optimized for ease of use and safety.

Data & Records Management

It's normal practice for many biomedical, pharmaceutical, and medical device companies to interface with the FDA and their requirements, which are considered throughout the device, drug, or product lifecycle. While a pre-market approval may not be needed for a medical device's packaging, packaging standards and records management should be taken seriously. Testing physical properties of medical packaging for a variety of parameters, and how accurate and reliable those results are, is all important information needed by the FDA.

This is where installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) to FDA 21 CFR part 820.76 are needed to validate the universal testing machine that's used to test the medical packaging. Many companies establish their own IQ/OQ/PQ process in their quality departments or require the mechanical testing equipment supplier to help support the process.

The purpose of the IQ/OQ/PQ process is to ensure the testing equipment being used is suitable for its purpose and is capable of producing valid results. The IQ process is designed to ensure that the system is installed and set up correctly. In addition, this process requires the recording of the installation conditions, operation of safety features, environmental conditions, and all appropriate services and utilities of the equipment. While the IQ process is perhaps the simplest part of IQ/OQ/PQ, it's good documentation practice to have it complete and readily available.

The OQ process verifies the correct operation of the testing system and validates the test results. For medical packaging labs, a validation plan could include system operation validation, verification of the force transducers, functionality checks of the software, and validation of key calculations, such as peak load and tear resistance.

PQ is the most complex part of the validation process. For a medical packaging laboratory, the PQ process validates different system configurations for different test types (e.g., peel test and tensile test), and ensures that different operators use the same protocol to achieve similar results.

WANT TO LEARN MORE?

WATCH A VIDEO



Axial and Torsional Testing Childproof Medicine Bottle to ASTM D7860-14 WATCH NOW



VIEW WEBINARS
GIVEN BY
OUR EXPERTS

Biaxial Testing In Biomedical Application

- Elena Mangano & Elayne Gordonov VIEW NOW

DOWNLOAD A WHITEPAPER

A Review of Medical Device Quality System Controls for Laboratory Testing Equipment

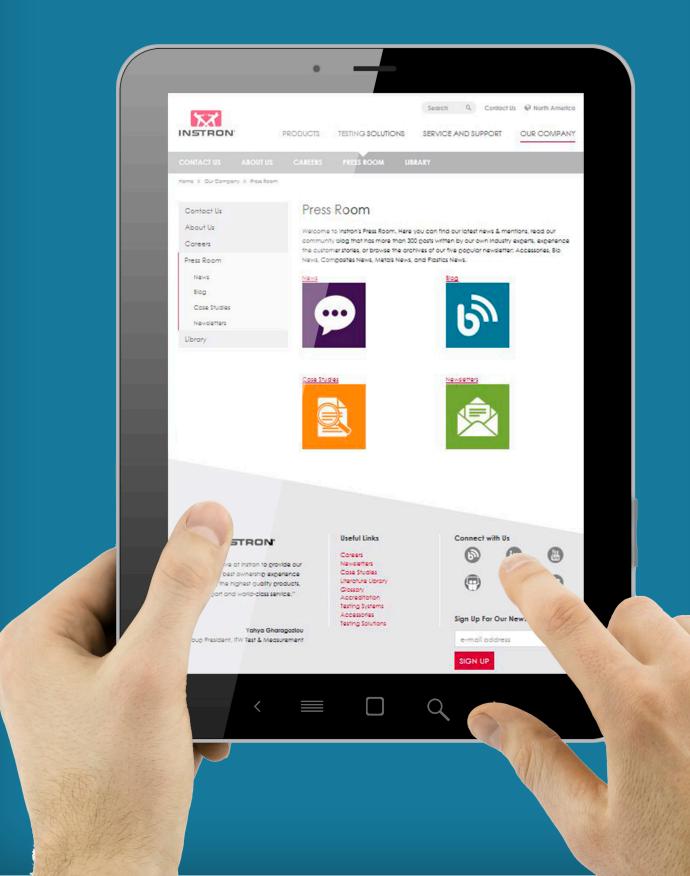
- Elayne Gordonov

DOWNLOAD NOW



WITH OUR NEW WEBSITE, STAYING CONNECTED HAS NEVER BEEN EASIER

Visit our Press Room to read ...





NEWSLETTERS

Application-focused newsletters are geared to their specific markets and are designed to keep you up to date on the latest happenings through downloadable white papers, industry and events updates, new product announcements, and much more.

Accessories News

TrendTracker™ Data Analysis Software



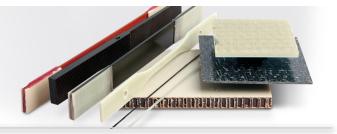
Bio News

Challenges in Torsion Testing for Biomedical Applications



Composites News

Nadcap Alignment Requirements: Instron's New Methodology Approved by NVLAP



Metals News

Advances in Using Strain Control



Plastics News

Common Mistakes Leading to Non-Compliance (ISO 527 & ASTM D638)







This new partnership is crucial to the success of our research and product development. It comes down to our need to partner with a company we can trust.

- Harri Hallila, Founder, Synoste



Community Connections

Instron® is focused on making a difference in the everyday lives of not only our customers, but also those that live in our community. In 2015, we contributed to:

- Norwood Food Pantry Food Drive and Day of Caring
- Trustees of Reservations Day of Caring at Powisset Farm
- Pearl Street Cupboard & Café Volunteering
- Understanding Engineering Day 150 high school students learned about Engineering
- . United Way's Hope for the Holidays Drive
- United Way's Feed-a-Family for Fifty Program

CONNECT WITH US



Update your subscriptions and interests to receive the latest testing news



Visit the Instron Community Blog



View upcoming events and the latest news



Have feedback or questions? Let us know what you think!

Find out more about the products and services Instron has to offer: www.instron.com