AUTOINJECTOR TESTING SYSTEM

Semi-Automated System for Testing Pen and Autoinjectors to ISO 11608

INSTRON®

AUTOINJECTOR TESTING SYSTEM

Semi-Automated System for Testing Pen and Autoinjectors

Developed in close partnership with pharmaceutical device manufacturers, Instron's latest generation Autoinjector Testing System can perform full functionality testing on a wide range of drug delivery devices – including needle shield and button-activated devices, as well as safety syringes.

Instron's Autoinjector Testing System measures a variety of essential performance requirements, including cap removal, dose accuracy, activation force, injection time, needle depth, and needle guard lockout – allowing labs to meet internal quality requirements and international standards such as ISO 11608.

CAP REMOVAL

DOSE ACCURACY

ACTIVATION FORCE

INJECTION TIME

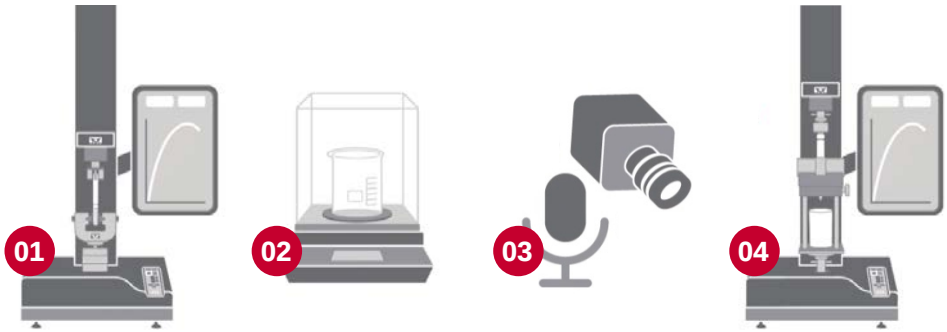
NEEDLE DEPTH

NEEDLE GUARD LOCKOUT

CLICK DETECTION

AUTOINJECTOR TESTING SYSTEM

Semi-Automated System for Testing Pen and Autoinjectors



Due to the complexity of autoinjector devices, labs often require multiple pieces of equipment to perform the wide range of tests required. This approach is more time consuming, requires more specimens, and creates a need for data consolidation.

Simplify the Testing Process

Instron's Autoinjector Testing System replaces traditional test procedures that require separate pieces of equipment, enabling users to run a complete sequence of tests on a **SINGLE SYSTEM**. This allows labs to accelerate time to market by:

- **REDUCING TIME** and number of devices required to complete testing
- **SAVING MONEY** on testing equipment, maintenance, and specimens
- **SIMPLIFYING** data consolidation, analysis, and validation processes
- **STREAMLINING** tech transfer to production sites

FULL FUNCTIONALITY TESTING WITH A **SINGLE SYSTEM**

CAP REMOVAL

ACTIVATION FORCE

CLICK DETECTION

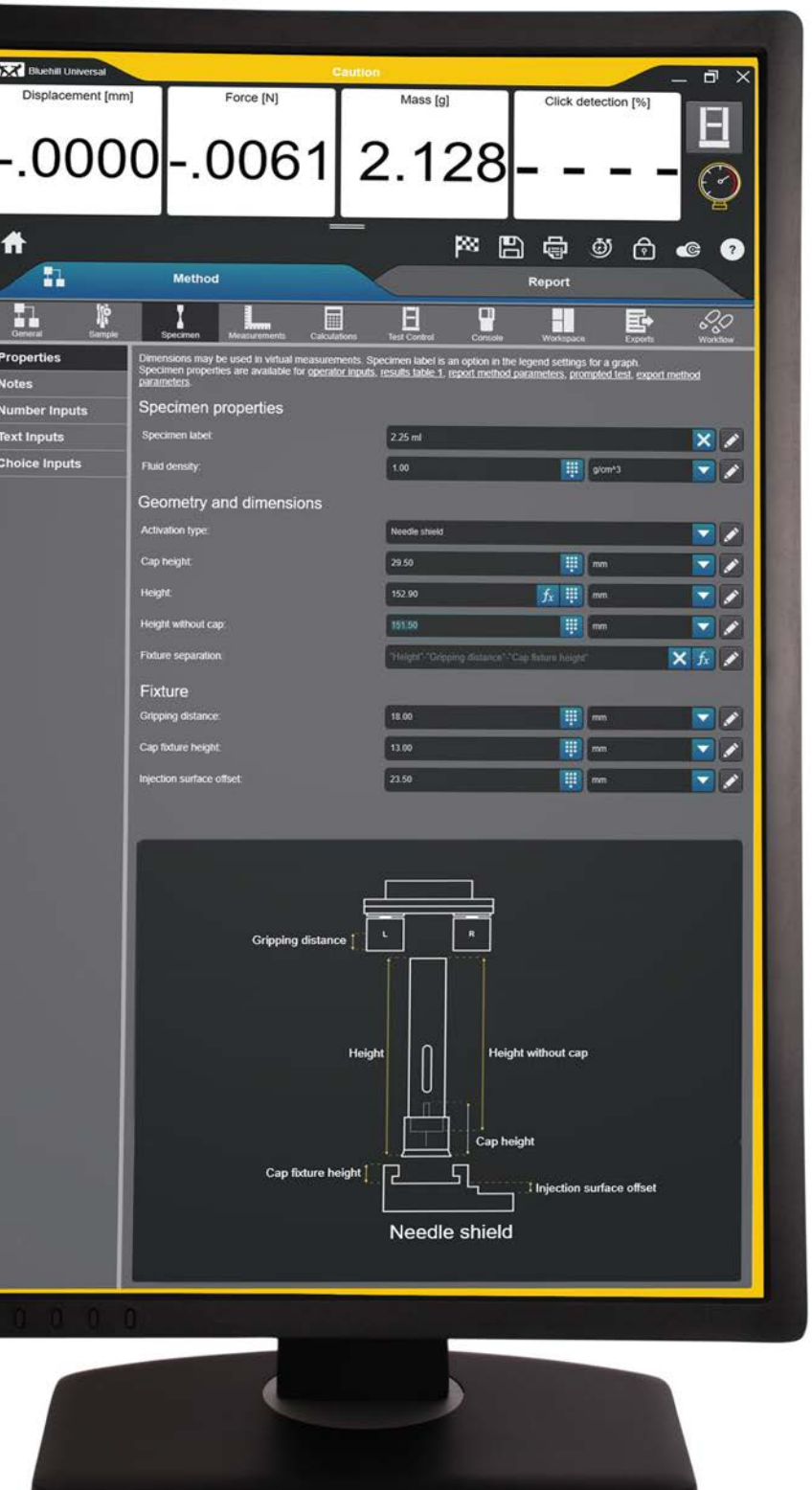
INJECTION TIME

NEEDLE DEPTH

DELIVERED VOLUME

INJECTION

NEEDLE GUARD LOCKOUT



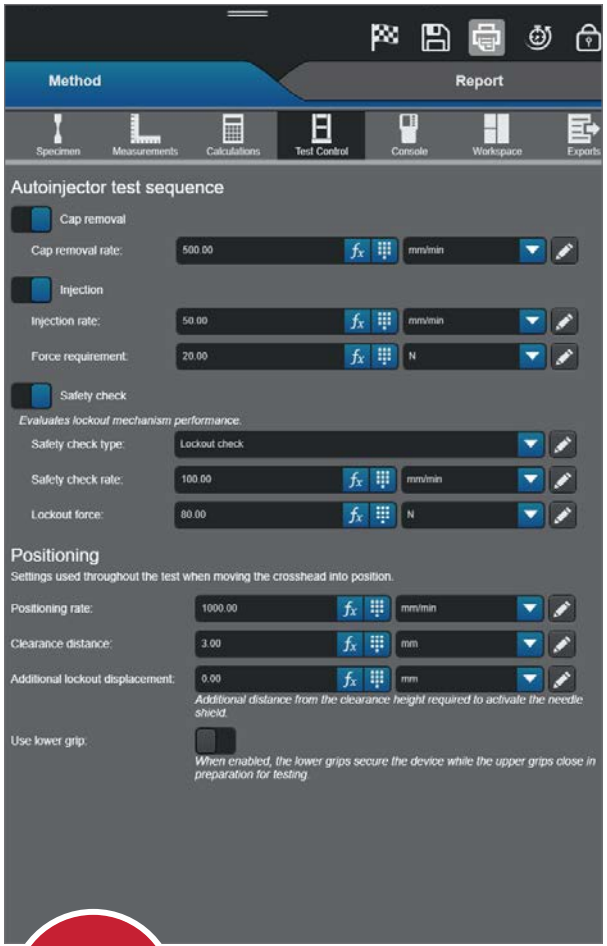
BLUEHILL® UNIVERSAL

Dedicated Test Methods

Bluehill Universal uses simplified test types that empower users to develop and change method parameters with ease, while offering the flexibility to readily accommodate future devices without requiring Instron's support.

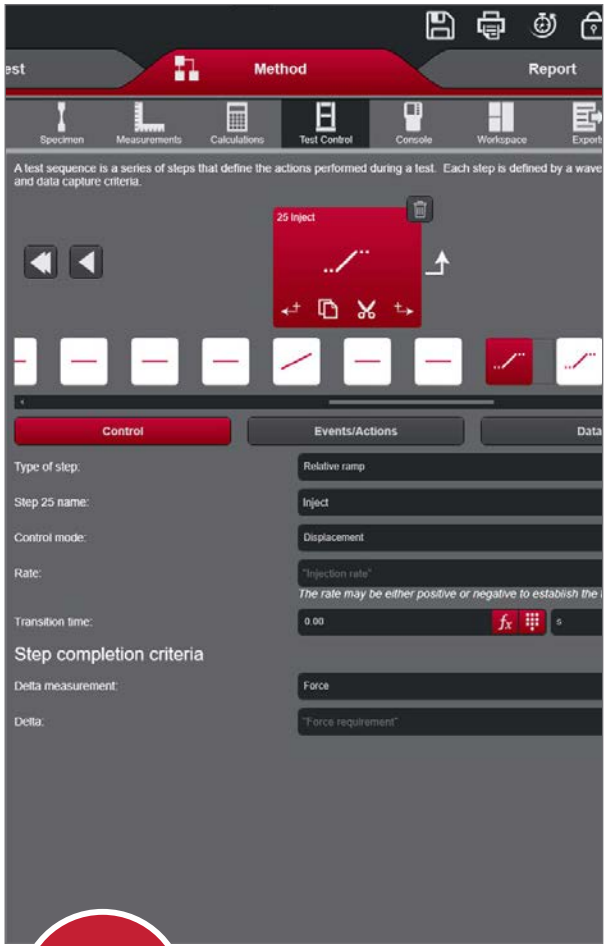
Device Properties

Button and needle shield devices are options in the specimen properties tab. The device type is selected and dimensions are entered. These dimensions are used to properly position the crosshead throughout the test sequence, optimizing test time and ensuring tests are run consistently, even on different systems.



Simple Test Method Type

Users simply select the required functional tests – cap removal, injection, and safety check of the needle shield – and enter the parameters. The system automatically runs the tests in the appropriate sequence.



TestProfiler Method Type

TestProfiler allows users to customize the standard test method parameters, providing greater flexibility when designing new devices.

Pre-Loaded Templates

Pre-loaded templates for needle shield, button activated, and safety syringe devices are included with the software, making it fast and easy for a user to create a new device method and begin testing.

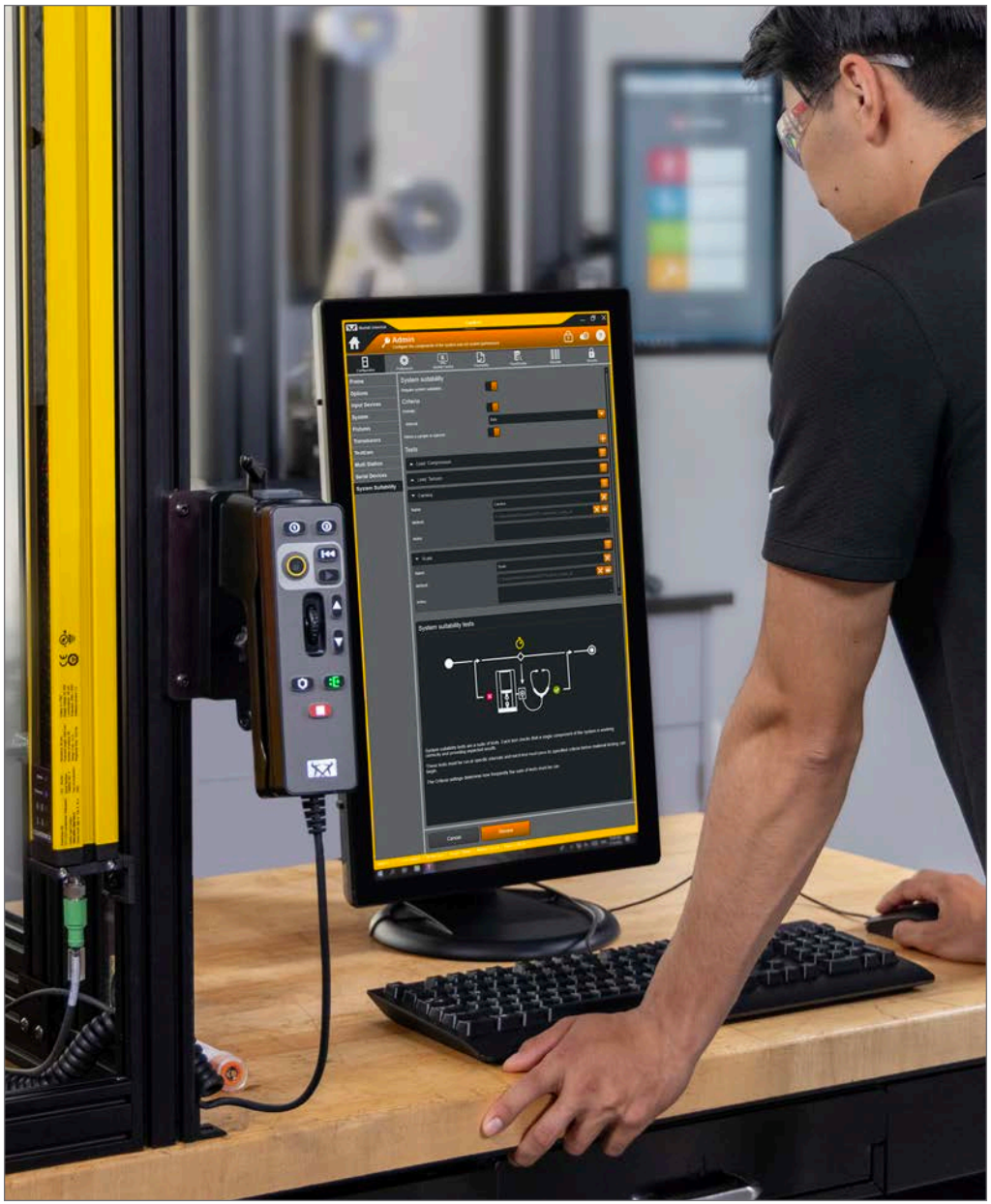
SYSTEM SUITABILITY TESTING

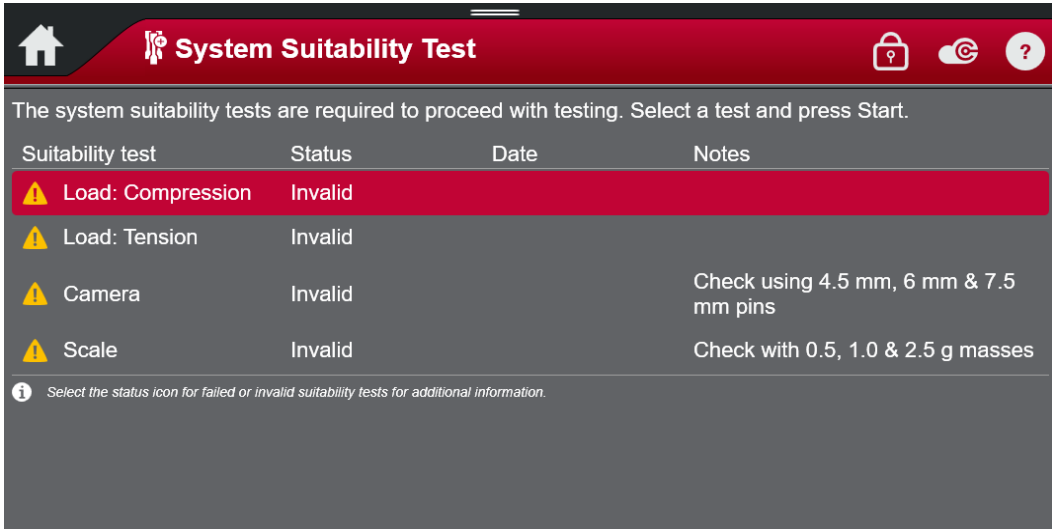
Improved Compliance in Bluehill® Universal

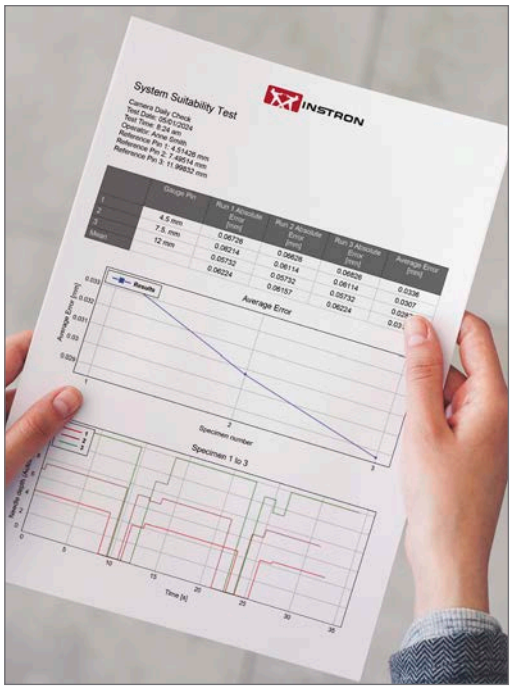
Bluehill Universal's autoinjector testing software integrates system suitability testing into its workflow, prompting users to perform tests and automatically tracking results in the audit trail.

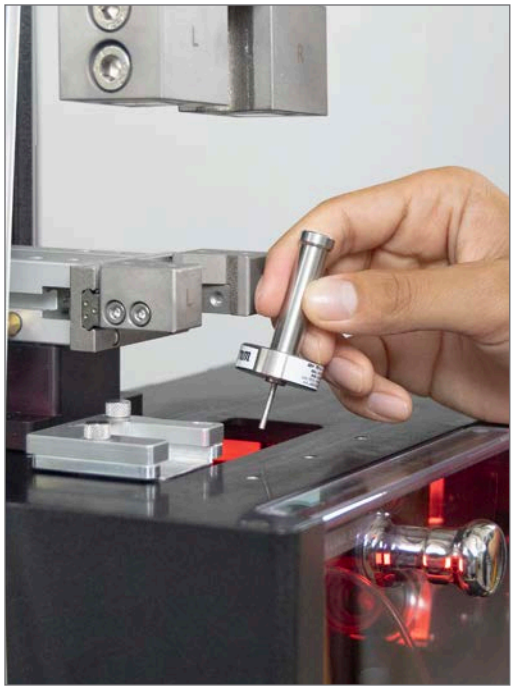
Good Manufacturing Practice (GMP) labs require daily checks of transducers prior to testing to ensure they are functioning accurately. In-house development of the hardware and test methods for performing these checks are time consuming and difficult to validate. Often labs use paper records to track the completion and performance of these daily checks, leaving them vulnerable in an audit.

Bluehill's new System Suitability Testing (SST) feature reduces the risk of audit issues and improves GMP compliance by requiring users to perform daily verification checks on the load cell, machine vision camera, and scale. The system prompts the operator to complete these checks based on requirements set in the administration settings.









Enforced System Suitability Testing

A system administrator can turn on the SST requirement and specify which transducers must be checked as part of the process. Frequency of SSTs are also set by the administrator based on a time period and/or upon the creation of a new sample. Bluehill Universal will prevent additional device testing until the SSTs have been successfully completed.

Traceability

A report of the system suitability results is stored as a PDF and the successful completion of these checks is recorded in the audit log of the Traceability module, offering an efficient way to comply with the audit requirements of FDA 21 CFR Part 11 and other accrediting bodies. IQ/OQ services offered by Instron Service are available to accelerate the validation process.

Hardware Kit

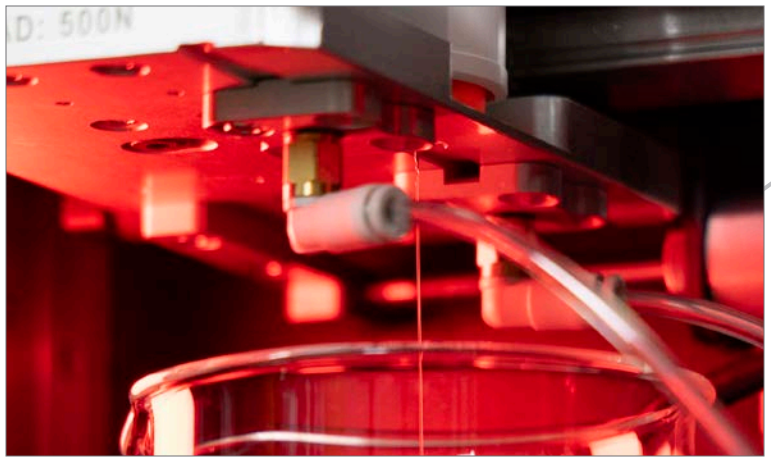
Instron's turnkey solution is completed with the supply of a hardware kit to check each of the transducers allowing users to validate force and mass readings, and needle depth measurements. This kit is easy to use and accelerates the validation process.

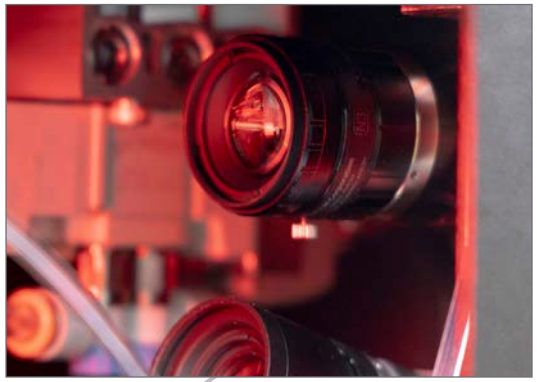
MACHINE VISION CAMERA

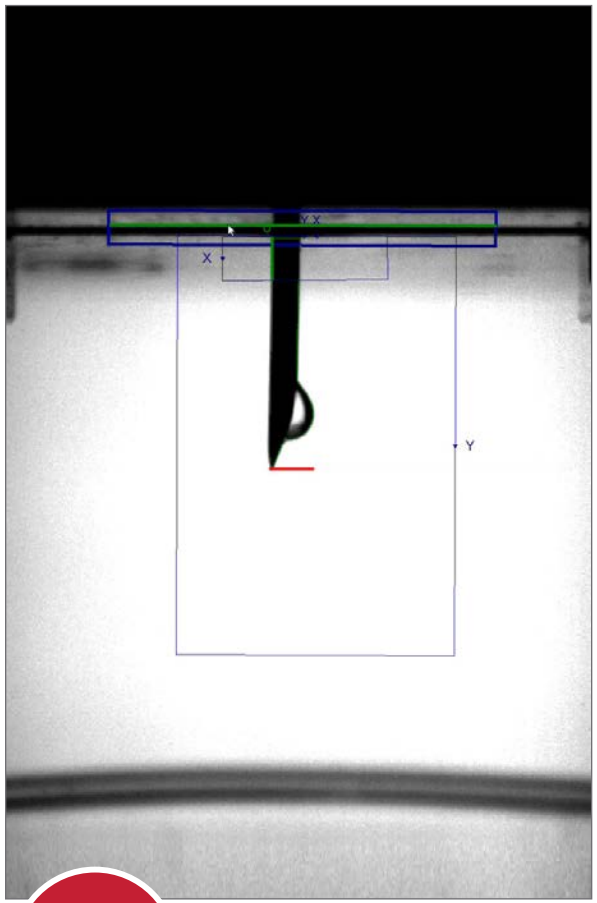
Needle Depth and Injection Time

Instron's system incorporates a machine vision camera to provide a measured injection time as well as indications of the exposed needle depth at both the start and end of the injection.

Measurement of the injection time and needle depth during the injection of the fluid is a critical piece of data to ensure the device is working as therapeutically intended. The use of an optical measurement method to capture this data is more effective than traditional methods, such as gravimetric or laser-based systems, especially as drug formulations and device activation mechanisms evolve.

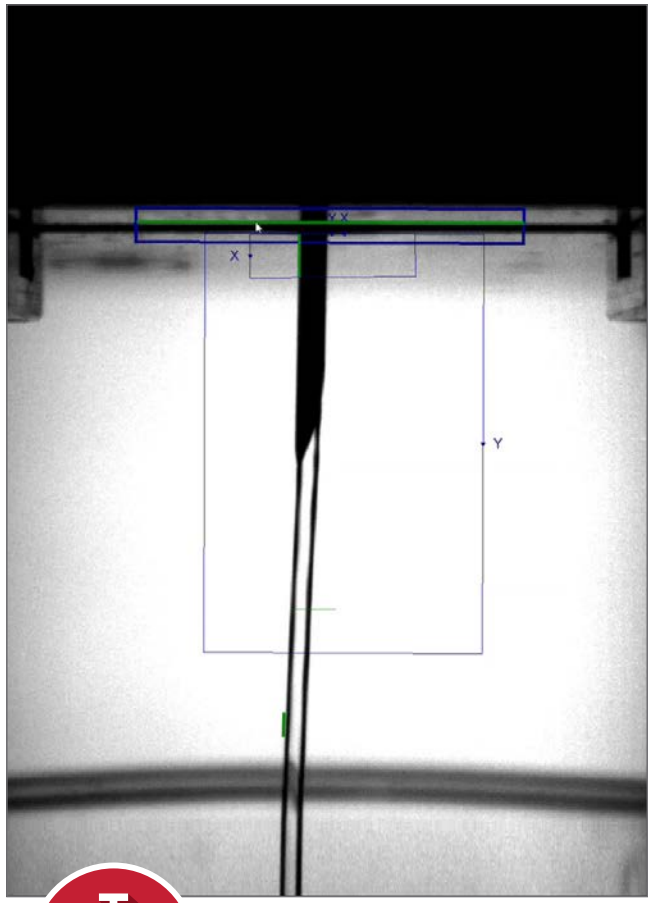






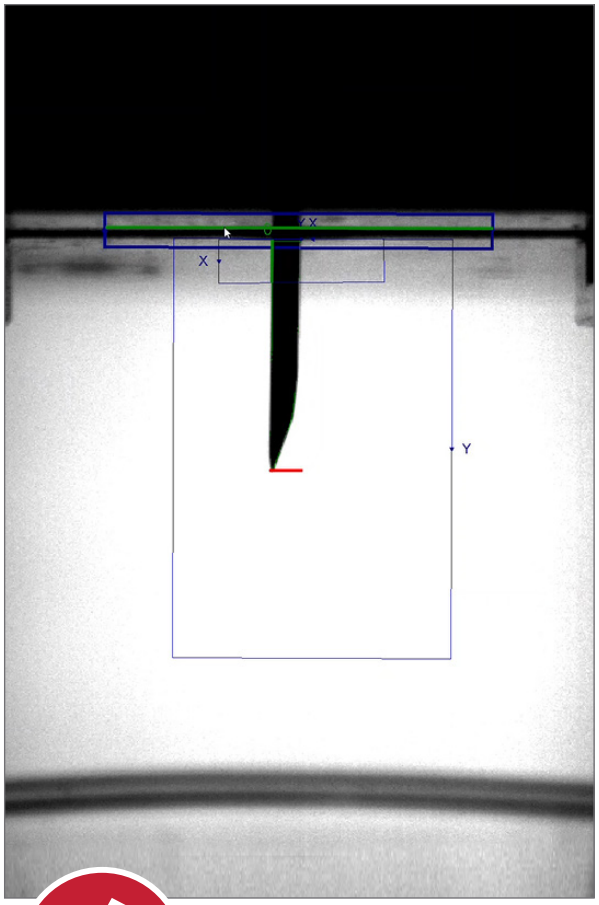
Needle Depth at Start of Injection

A measurement of the needle depth when the initial fluid expulsion occurs provides the ability to identify whether the device is delivering its dose into the therapeutic range. This measurement can be brought into Bluehill Universal. A photo of this event is stored, making it available for analysis any time after the test has been completed.



Measurement of Injection Time

The machine vision camera provides high accuracy measurements of injection time, which supports a wide range of delivery profiles, including high viscosity formulations with non-continuous streams. This technology also supports newer device activation technologies, such as gas powered and electromechanical, that have shorter injection times that cannot be adequately characterized with a scale.



Needle Depth at End of Injection

The machine vision camera measures the needle depth at the end of injection and sends that value into Bluhill Universal. An image at the point the measurement was taken is stored to provide evidence that measurement was taken at the correct time, as well as to serve as a post-test analysis tool when needed.

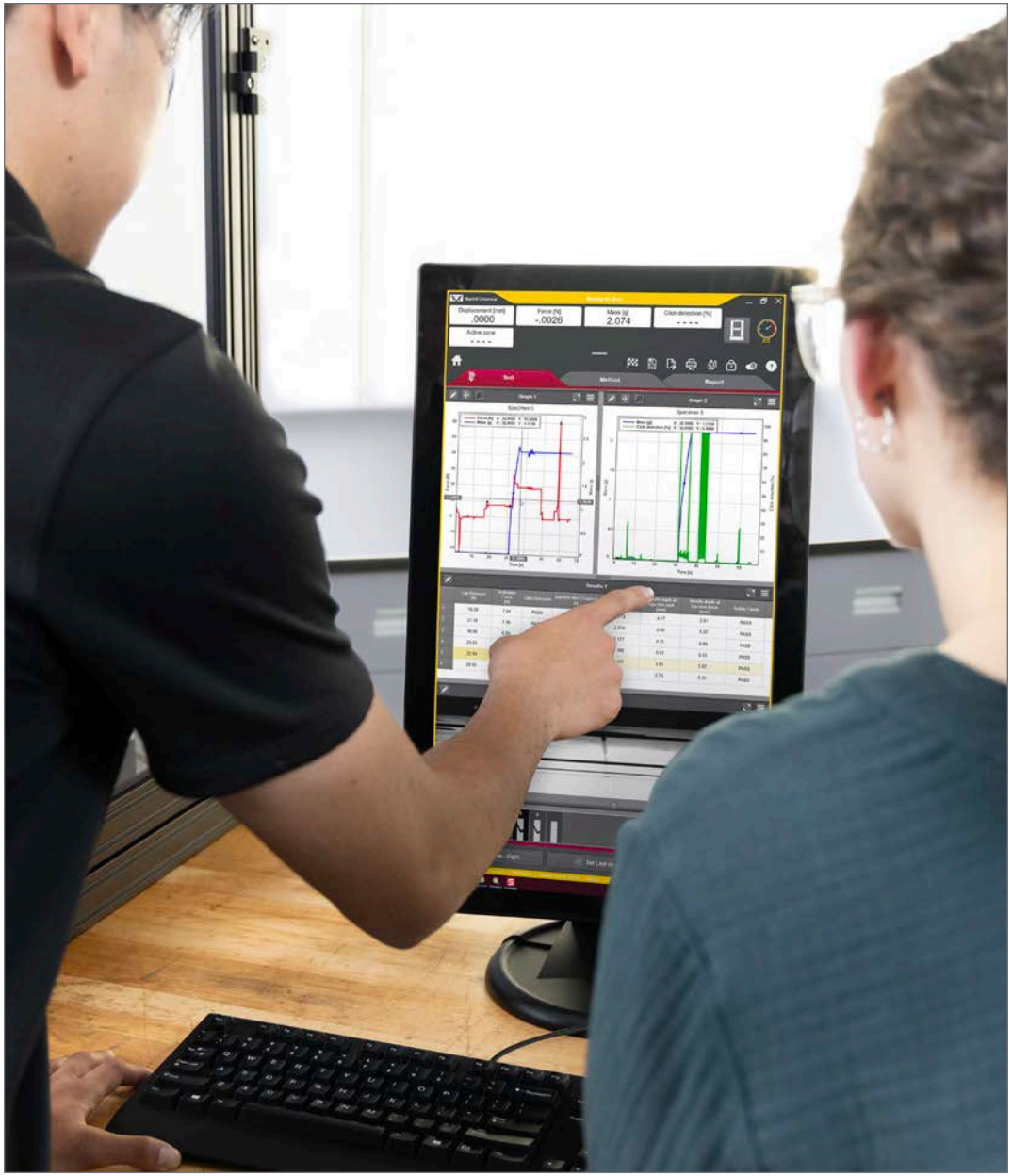
ROOT CAUSE ANALYSIS

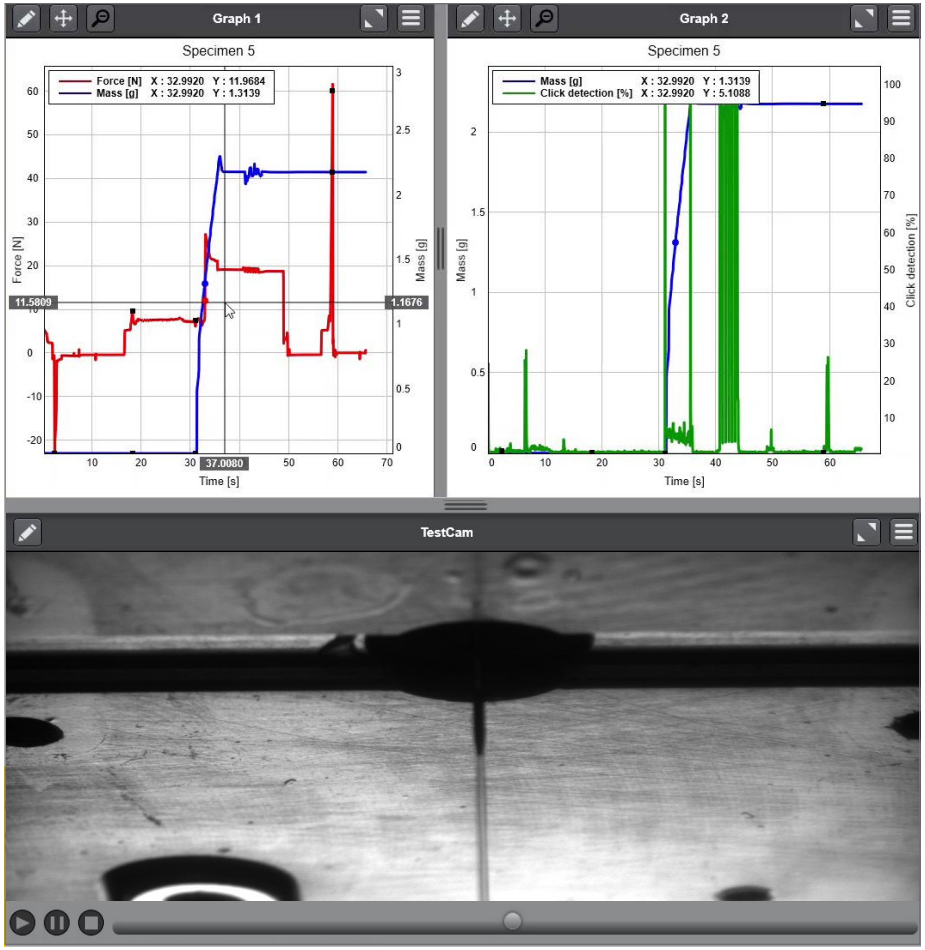
High-Resolution Video Camera

Instron's Autoinjector Testing System uses a high-resolution video camera, along with the machine vision camera, to provide critical visuals to aid in root cause analysis when a device failure occurs.

Some device failures are clearly detectable based on the calculated results, data curves, or the appearance of the device itself. Other failures are not obvious until the entire sample batch has been tested and statistically analyzed (K-value). In either scenario it is important to determine whether a bad result was truly a device failure or simply the result of a testing error. Root cause analysis for failed devices can be an extremely time-consuming process requiring significant retesting and leading to costly delays.

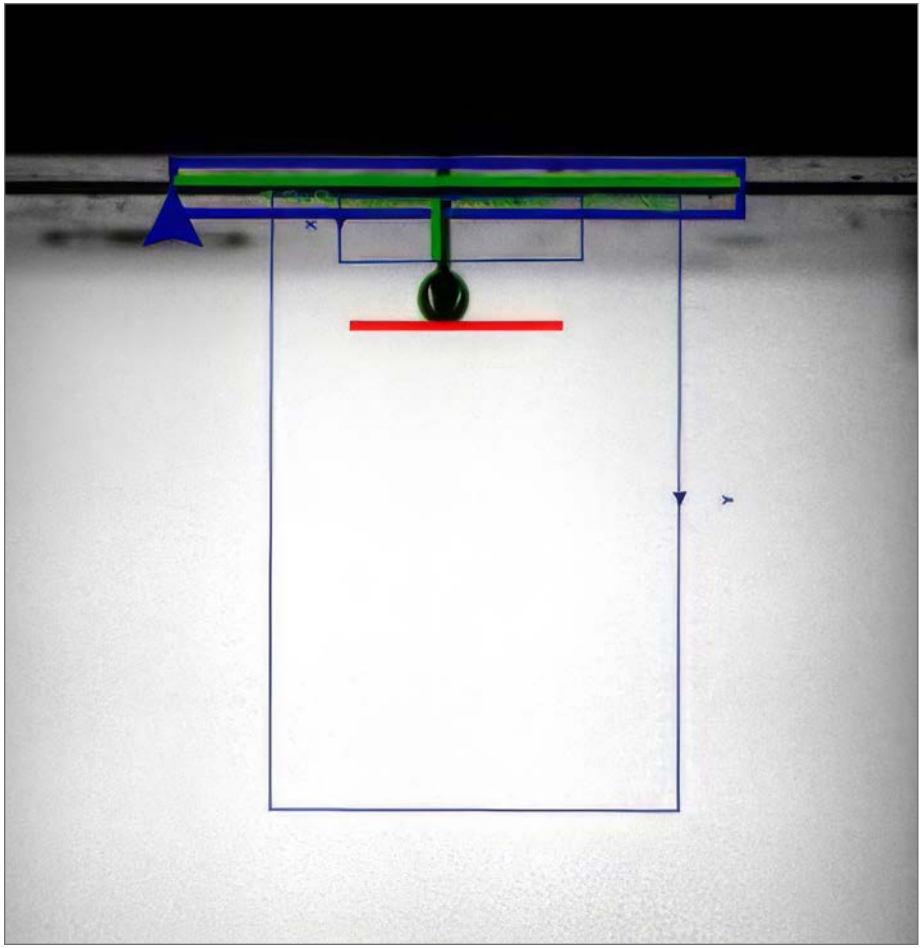
The autoinjector system's high-resolution camera records a video of the injection. Visualizing the injection provides useful insights to understanding discrepancies in delivered volume, needle length, and injection time. In addition, the machine vision camera used to measure injection time and needle depth captures injection images that provide insight into the accuracy of the needle depth calculation. These capabilities provide the means to analyze sample results post-test and reduce the time required for root cause analysis studies in production environments.





Video Recording of Injection

A high-resolution camera monitors the injection and records a video. This video can be viewed and replayed through Bluehill's TestCam module, allowing further analysis to be performed on a previously run test. When the video is replayed the closest corresponding data point on the test curve is highlighted. Conversely, a scanning cursor can be used to select a particular point of interest on a data curve which pulls up the associated video frame.



Needle Depth Image Storage

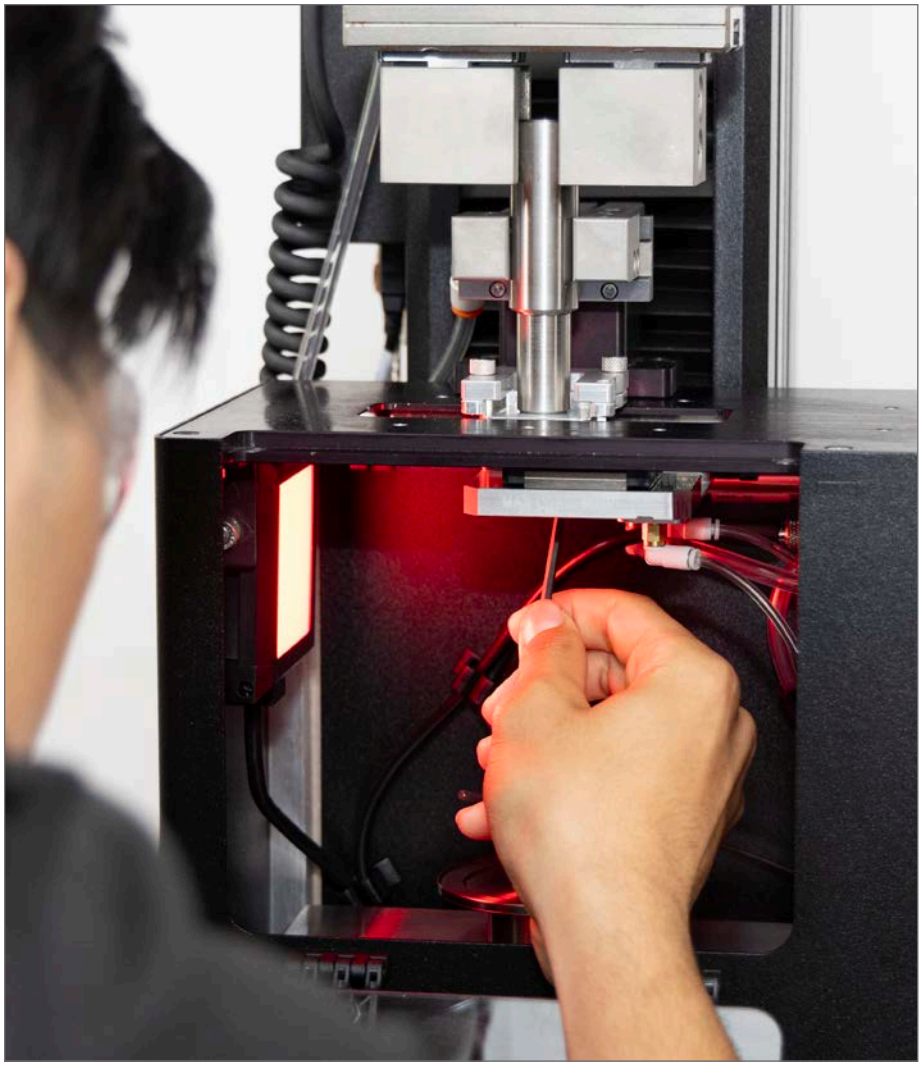
Images of the needle at both the start and end of the injection are stored for each device. The image at the end of injection includes an overlay that clearly depicts where the measurement was taken. This provides evidence of whether the measurement is correct or was adversely affected by the presence of a last drop, a defect in the device, or an error in the test setup.

DEVICE FLEXIBILITY

Device Changeover and System Alignment

Instron's Autoinjector Testing System's fixtures are designed to minimize side loading during cap removal and support common industry device geometries, while offering flexibility to easily accommodate customized devices.

Variability in cap removal force measurements is directly impacted by system alignment and insert design. Instron's simplified cap removal fixture consists of a common base and device-specific inserts that are easily interchangeable. The base is aligned to the grips and crosshead and does not need re-alignment unless it is removed. To accommodate a new device, the insert is simply changed out using three thumb screws.



System Alignment

In the instances where alignment of the Instron system is required, the alignment procedure, using the included fixture, is simple and repeatable.

Cap Removal Insert

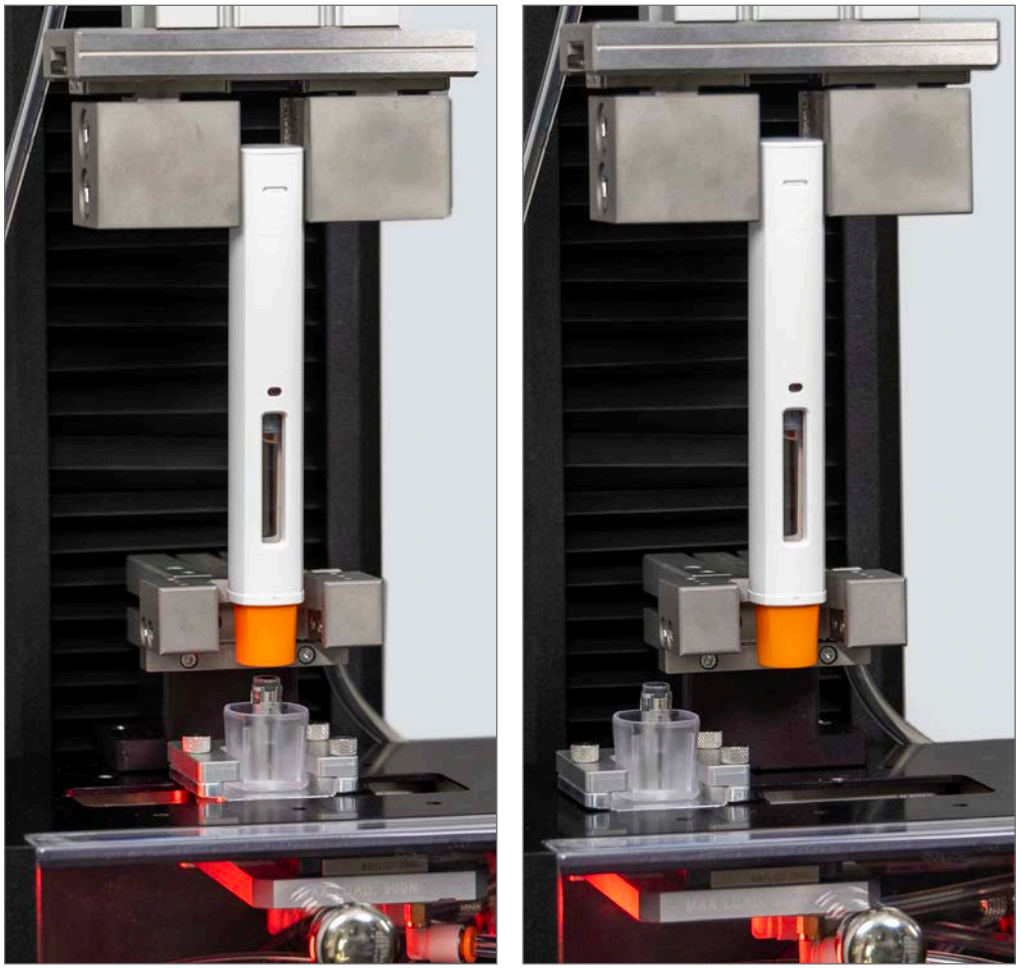
While a range of inserts for the common commercially available autoinjector devices is supplied with the system, the design simplicity makes it easy to machine new inserts for customized devices.

HARDWARE OVERVIEW

Semi-Automated Autoinjector Testing System

Light Curtain

The system is enclosed on three sides, with a light curtain across the front to prevent operation of the machine when the operator is physically in the test space. Optionally, a clear panel may be installed on the front of the system to provide a physical barrier.



Pneumatic Shuttle

After removal, the cap is moved out of the test space by a pneumatic shuttle, allowing the system to transition directly into the injection test.

01 Pneumatic Grips - Defeat Force Rated

Rated to 500 N, to allow complete device testing, including defeat force tests on the needle guard. Grip pressure is stored within the test method, ensuring consistency between tests, even those run on different systems.

02 Last Drop Blowoff

After the injection is complete, bursts of air remove the last drop of fluid from the needle before the final injection depth is measured. The air channels are positioned to minimize turbulence on the fluid collected in the beaker.

03 Machine Vision Camera

Provides needle depth measurements at both the start and end of the injection, as well as injection time.

04 High-Resolution Video Camera

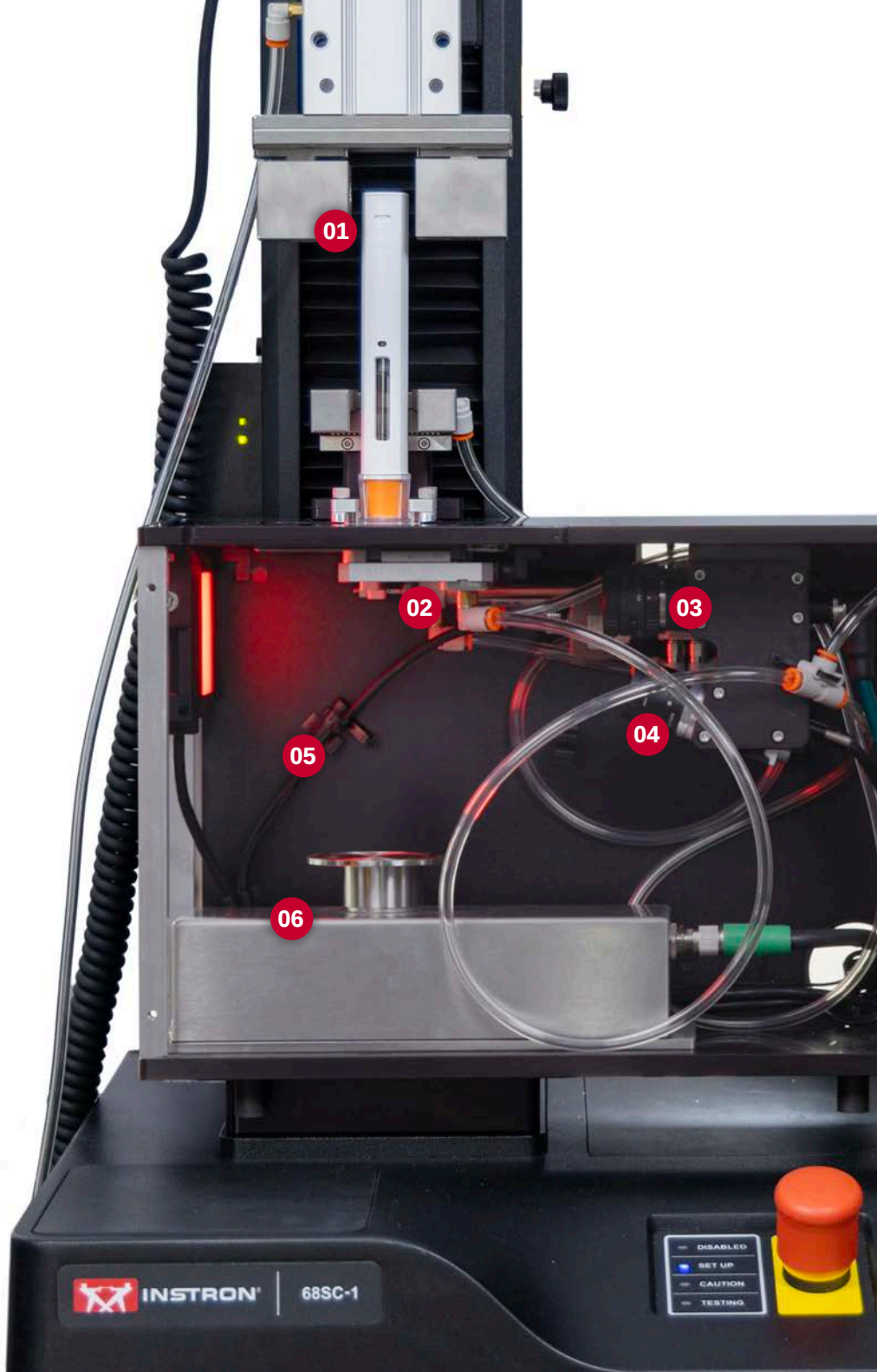
Provides a video recording of the injection for data records and post-test analysis.

05 Microphone

Located close to the injection site within the test box to minimize the effects of environmental noise, the microphone clearly detects first and second clicks. This signal is brought into Bluehill Universal software, where it can be plotted in real-time and stored with the rest of the test data.

06 Precision Scale

A precision scale is used to measure the injection mass and volume (derived), and injection time. The weigh pan, designed for use with two common beaker sizes, restricts movement of the beaker, ensuring it is always centered directly beneath the injection surface.



VALIDATION SUPPORT

Compliance Software and Service

Instron® offers a complete turnkey system, including products and services to help users accelerate their in-house validation processes and put their system into use.

Traceability

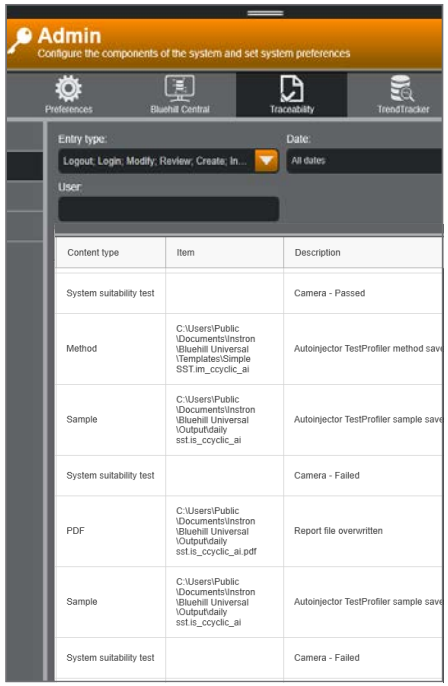
Bluehill Universal's Traceability module enables users to meet the audit requirements associated with FDA 21 CFR Part 11, ISO 17025, Nadcap, and others, providing unmatched data traceability. Bluehill Central software enables centralized, remote management of multiple Instron test frames, including management of all Bluehill Universal users, test templates, results, file revision approvals, and audit trail data from multiple Instron systems.

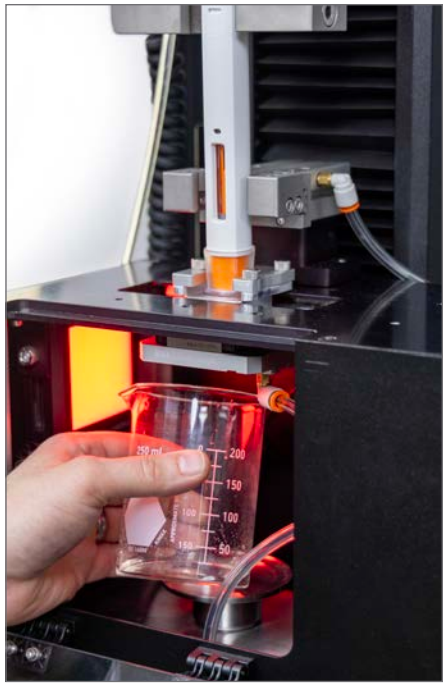
On-Site Calibrations

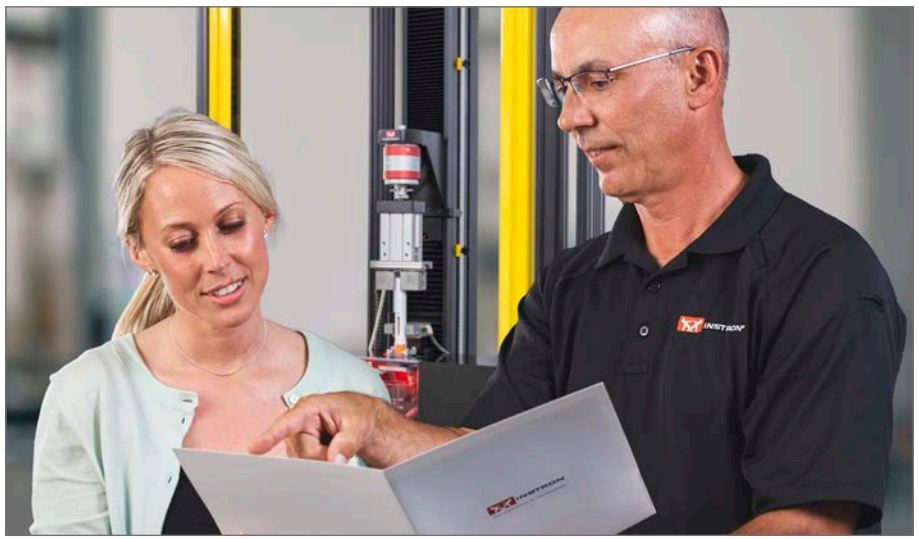
Instron Professional Services offers on-site calibration services for the Autoinjector Testing System, including tension and compression force, speed and displacement, and needle depth. These services ensure that testing parameters are being met and that associated results are being calculated accurately.

IQOQ Validation

Software validation is critical for compliance with FDA 21 CFR Part 820, also known as the Quality System Regulation (QSR), and ISO 13485. Instron offers vendor Installation Qualification and Operational Qualification (IQOQ) documentation, which is completed at your site by trained Instron Field Service Engineers. This validation is designed to ensure that your Instron testing instrument has been installed correctly, is suitable for its intended purpose, and is capable of producing valid results. Our experienced Service team will use Instron's proven documentation pack which contains necessary IQOQ documents, reference files for calculation validation, and manuals.







COMPATIBLE DEVICES

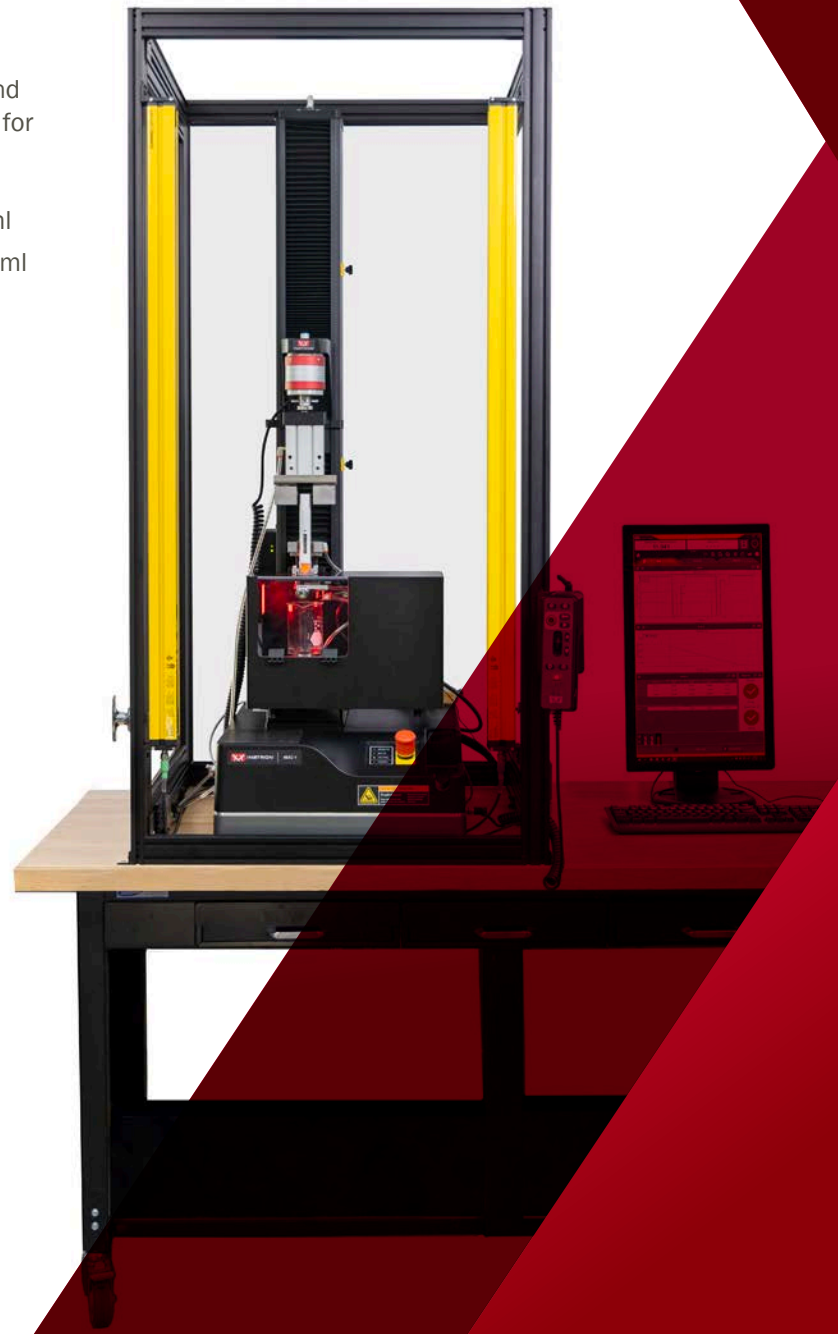
The Autoinjector testing system is compatible with most standard needle shield and button activated devices, and safety syringes. The system is supplied with fixtures for the following standard devices*:

BD - Physioject™
BD - Intevia™ 1.0 ml
Halozyme - QuickShot®
Halozyme - Vibex®
SHL® - Molly® 2.25 ml
SHL® - Molly® 1.0 ml
SHL® - DAI®
Ypsomed - YpsoMate™ 1.0 ml
Ypsomed - YpsoMate™ 2.25 ml

* Cap removal inserts are designed to work with autoinjector devices built to standard manufacturer specification. Customized devices may require a different insert.

SYSTEM SPECIFICATIONS

Dimensions - Enclosure Included (h × w × d)	**mm** **in**	1500 × 740 × 764 59 × 29 × 30
Needle Depth Measurement	**mm**	3 - 20
Minimum Injection Time	**sec**	0.15
Scale Capacity	**g**	220
Maximum Load	**N**	500
Power Requirements	**-**	Single Phase, 120 or 240 VAC ±10%, 47-63 Hz
Operating Temperature Range	**°C** **°F**	+10 to +30 +50 to +86
Operating Humidity Range	**-**	50 - 80%



THE WORLD STANDARD

We stake our reputation on the integrity of data. From the measurement of primary test data to result generation, we design and manufacture the full data integrity chain (e.g. load cells, sensor conditioning, and software). Additionally, we calibrate more than 90,000 of these sensors annually with the lowest accumulated uncertainty.

30,000+

We service and calibrate more than 30,000 Instron systems in active use worldwide every year.

96%

96% of the Fortune 100 list of the world's largest manufacturing companies use Instron test systems.

18,000+

Instron systems have been cited in more than 18,000 patents since 1975.

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