



Why Automation May Be the Perfect Affordable Solution for Your Testing Challenges in the Medical Industry

The highly dynamic nature of the development, production and application of medical devices demands testing processes that not only keep pace but remain standard-consistent and are subject to high safety standards. Materials testing solutions that play catch up are not an option in this industry, leading experienced manufacturers to work closely with international standards committees to exchange knowledge and support the development of new requirements—which are continuously integrated in the design of new testing solutions. This allows materials testing machine and instrument manufacturers to provide standard-compliant solutions in synch with the latest requirement publications and ensure the highest possible quality of test results for their customers.

As requirements become increasingly more intricate, accuracy, precision and reliability are not just buzzwords, but rather unforgiving principles that define the only acceptable testing process and results. In a labor market where qualified testing lab personnel is beyond scarce, medical device manufacturers and quality assurance supervisors rely on standard operating procedures that detail every step of the testing process with the expectation that operators will meticulously follow suit. For some, this process works, while for others it presents an additional challenge that affects not only quality but also time. But what if automation, even at a small scale, can turn expectations into concrete, 100% standard-compliant processes and results?

Clearly, the medical industry is one of the most strictly regulated in terms of not only medicine, but also biomedical devices and drug delivery systems. Materials and components and testing of the devices themselves, therefore, plays a crucial role in the quality assurance, and product approval and acceptance process, and more importantly, in the safety of every patient. In this white paper, in addition to the above-mentioned realities of materials testing in the medical industry, we will take a closer look at some key operational challenges. We then look at why automation can provide a highly effective solution to each of these challenges and increase the throughput of testing. Finally, we conclude by addressing some common misconceptions about automation that prevent some organizations from realizing the discussed benefits.



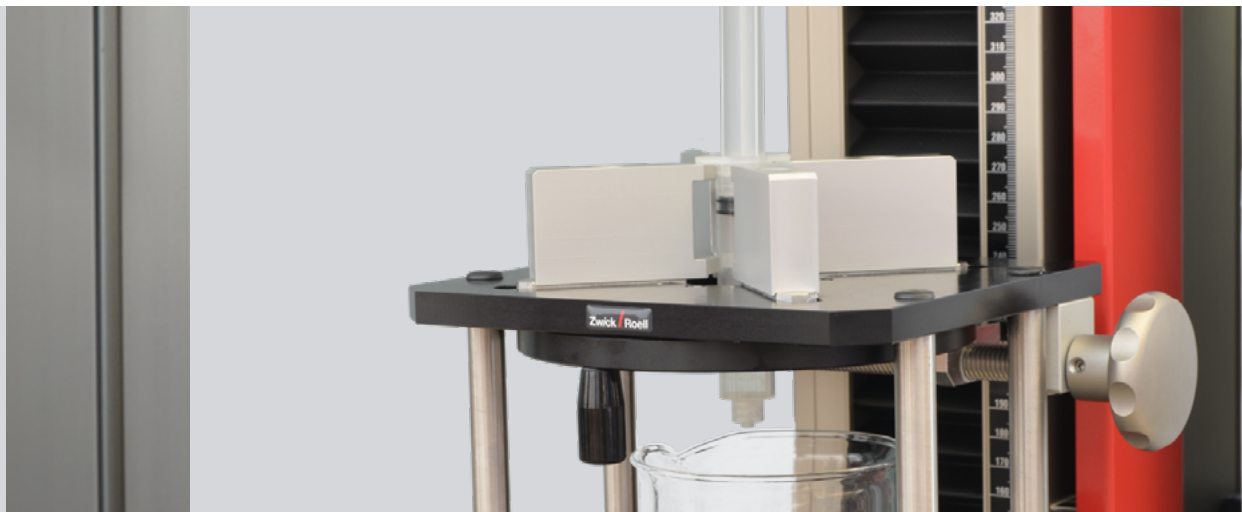
Important Operational Challenges in Device, Materials and Component Testing

Especially in the medical industry, materials and component testing creates unique operational demands for precise, accurate, repeatable, reliable work. Workflows must be repeated by-the-book every time (even when being performed by different technicians at different labs). And data must be captured and reported with near-perfect accuracy.

These requirements constitute day-to-day challenges for testing operations of any scale. Fortunately, automated materials testing can help.

The most impactful automated testing solutions should help directly address each of the following four challenges:

- **Avoiding Operator Error:** from specimen handling to manual data entry, any point where an operator interacts with the materials testing process is a potential source for measurement problems, data recording errors, or other issues. With a growing shortage of qualified laboratory technicians, supervisors rely on well-defined SOPs, which serve to guide but cannot guarantee the prevention of errors.
- **Repeatable and Reproducible Results and Reporting Across Multiple Technicians and Testing Sites:** ensuring repeatable testing is always challenging, even more so for companies that conduct testing across multiple sites (distributed across a continent or around the world). Collecting and validating testing data while maintaining consistent procedures is essential for standard-compliance, ensuring consistent product delivery, and aligning organizational best practices.
- **Protecting the Time of High-Value Technicians:** manual testing processes require much more supervision than automated solutions. Scarce skilled technicians are often required to spend time performing monotonous tasks—or watching a testing machine and waiting for results.
- **Small Errors Add Up to Large Costs:** a seemingly small measurement error or simple missed keystroke can lead to liability and outsized costs if, for example, product needs to be recalled.





How Automated Testing Systems Address Key Materials Testing Challenges

The key value of an automated materials testing solution is its ability to directly address each of the four common challenges discussed above.

In addition to offering faster, more efficient testing that accommodates higher throughput, automated testing solutions drive added strategic value by limiting operator error, streamlining data reporting, and allowing technicians to focus more time on value-added activities. By limiting the risk of medically unacceptable and costly testing failures, automated solutions can drive substantial long-term ROI.

We take a deeper look at each of these benefits in the sections below.



Automated Material Testing Benefit One:

Reduced Operator Touchpoints Limit Errors

Any part of the testing process where operator interaction can be removed represents reduced risk of error. Automated testing solutions can provide precise, accurate measurements through procedures that are perfectly repeatable over time. Even automated data export can help ensure quality results by eliminating manual data entry errors and/or non-standard reporting practices.

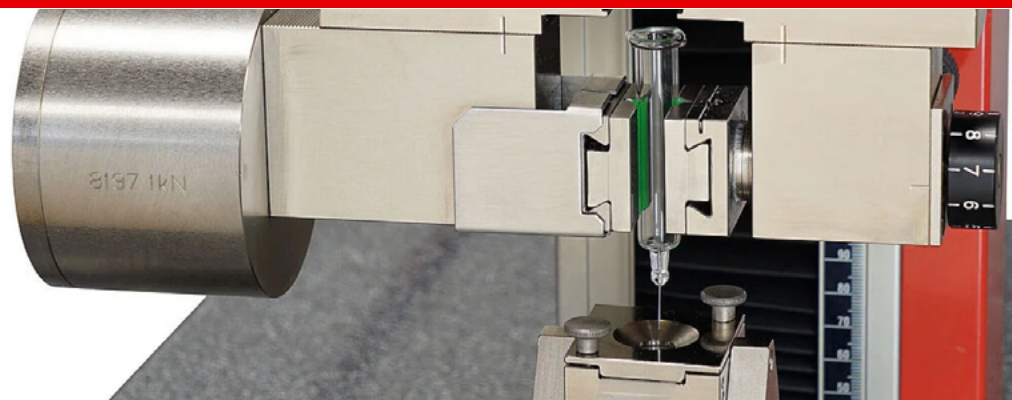


Automated Material Testing Benefit Two:

Integrated Data Reporting Improves Consistency and Streamlines Multi-Site Testing

Integrated data reporting ensures that automated testing solutions drive consistent reporting across the organization. In addition to reducing data entry errors and streamlining data management, integrated reporting is hugely valuable for organizations that manage multiple testing sites, while adhering to strict national and international industry standards. For example, *using ZwickRoell's testXpert software, a centralized quality assurance department can easily monitor testing results for all sites in the organization*—data is downloaded and accessible in real-time via the company network.

For safety-critical tests with special documentation requirements, testXpert additionally ensures that your test results are traceable in accordance with FDA 21 CFR Part 11. The regulation 21 CFR Part 11 on electronic records and electronic signatures of the United States Food and Drug Administration (FDA) defines acceptance criteria for the use of electronic records and electronic signatures in place of records in paper form and handwritten signatures on paper. These electronic documents must be handled with as much confidentiality, be just as authoritative, and hold the same value as the paper documents. Compliance with regulations FDA 21 CFR Part 11 and EU GMP guidelines Annex 11 is required for use with electronic records and signatures in a regulated environment. Electronic records prevent tampering and electronic signatures provide a paperless audit trail.





Automated Material Testing Benefit Three:

User Spend Less Time Waiting for Test Results

In a non-automated testing process, technicians perform many repetitive cycles of measuring the specimen, inputting data, inserting specimens, and waiting for results. In much of this time, a valuable lab technician is reduced to a data entry clerk, and even more time is spent waiting.

An effective automated testing solution can transform this entire process. Without needing to manually monitor the testing process, high-value materials testing experts are free to focus on other value-added activities. And, by offloading the most monotonous, time-consuming tasks to automated solutions, testing experts can focus on the testing processes that require careful input from a qualified technician.



Automated Material Testing Benefit Four:

Reduced Risk of Costly Testing Failures

This fourth benefit is a direct result of the reduced human error and improved data reporting discussed above. These capabilities drive substantial long-value ROI for automated testing solutions, particularly when compared to the significant costs that can accrue from testing failures that result in unhappy customers, regulatory penalties, or product recalls. In the long run, automated testing solutions constitute an effective risk-management investment, and a safeguard for organizational reputation for quality.



Why Any Size Lab Should Consider Introducing Automated Systems to Their Daily Routine?

More manufacturers than ever are harnessing automated materials testing to realize the benefits discussed above. While in our experience, many organizations that could otherwise benefit from automated testing are still unsure if it is the right fit for their unique business requirements, their view is often based on misconceptions. Of course, every business is different. But in some cases, misinformation, or the simple lack of information about automation prove unnecessarily limiting—and can cause businesses to leave value on the table.

In general, many professionals hear “automation” and imagine a large, automotive-style assembly line full of large robotic arms. While this type of solution may be right for some use cases, today’s automated testing solutions are much more diverse and flexible. They can help large testing facilities accommodate more throughput and scale operations seamlessly to match demand. But they can also be configured for small quality control labs or new manufacturers in early stages of growth.

Common Misconceptions About Automated Material Testing—And Why They Do Not Reflect Today’s Reality

MISCONCEPTION ONE

Automated Material Testing Systems Only Make Sense at a Large Scale

Automated testing can be employed efficiently at a variety of production volumes, and large facilities are not a prerequisite. Automated testing solutions can include fully automated testing laboratories that work 24/7, ***with automated guided vehicles (AGV's) to move specimens around the facility.*** And they also include more focused solutions, machines designed to collaborate with human technicians in their existing daily workflows, allowing skilled resources to offload monotonous, repetitive tasks.

Technologies like ***ZwickRoell's roboTest N lightweight robot*** allow for cost-effective automation of smaller series testing, tasks that have been largely relegated to manual work in the past. Integrated safety features (like sensors that shut off operation if external influences are detected) allow these solutions to be used alongside human technicians without expensive investments in locked off work areas. Graphic visualizations, available via mobile devices such as iPad, allow technicians to track testing status in real-time as needed.

User training of these smart robots is kept to a minimum through full integration of the solution into the ZwickRoell software environment. And foolproof coding of test configurations, including tools and specimen magazines with machine-readable codes, ensure safe and reliable testing.



MISCONCEPTION TWO

Automated Material Testing Systems Are More Costly Than Manual Materials Testing

A holistic accounting of cost often demonstrates substantial ROI for automated solutions. When compared to the costs of errors, time spent by technicians waiting for test results, occupational safety incidents, product recalls, operational delays, employee turnover and training, etc. the savings associated with automated materials testing solutions can be substantial.

Even small improvements in testing precision can drive savings through direct product cost reduction. More accurate testing results allow for tighter tolerances, which means less material used buffering tolerance margins. Even savings of a few cents per unit in relaxed tolerances can add up to substantial amounts for higher volume products.

Furthermore, for companies or laboratories operating multiple machines, the added testing capacity per machine that is provided by an automated system may allow them to consolidate testing down to fewer machine numbers, and possibly fewer operators. This, in turn, frees up a new surplus of machines, or even just one extra machine, that can be used for other R&D projects, for example.

MISCONCEPTION THREE

Automated Material Testing Systems Require Assembly Line-Style Organization

Automated testing solutions can be flexibly configured to reflect the operational needs of the facility where they will be employed. Today's automation solutions can be self-contained in a single piece of testing equipment that is tray-loaded by a technician. An automated specimen handling system may look nothing like a prototypical assembly line. ZwickRoell automation, for example, may be implemented as a table where a technician loads a specimen tray. Handling systems can be extremely flexible as well. **A single mobile robot, for instance, can feed several different testing systems, each one working at a different scale.** Specimen handling systems can be designed for both standardized ISO specimens and unique specimens. From there, specimens can be moved by conveyor belt, rotary systems, or other mechanisms, throughout the testing process.

With ZwickRoell, specimens are manually sorted into different magazines. After this point, virtually every aspect of the testing process can be automated, but not every part is required to be automated. Different levels of automation can be matched to the operational challenges at hand, and different measuring devices can be integrated anywhere in the testing sequence to reflect unique testing requirements. By leveraging the parallel processing of specimens, ZwickRoell automated solutions can deliver results significantly faster than even other automated solutions.



Automated Testing Solution Examples from ZwickRoell

Automated materials testing solutions can be applied to a wide variety of different testing processes. The list below includes just a few examples of ZwickRoell's offerings. While not exhaustive ([you can view our full list of automated solutions here](#)) this list demonstrates the immense diversity of solutions for medical device and delivery systems available today.

The specific implementation of each machine can be quite flexible. Robotic arms, for example, can be placed into park position to allow for manual testing when necessary. Multiple machines can be used in series, automatically feeding specimens into the next testing stage. A variety of optional components including barcode readers, temperature baths, specimen turntables, XY tables, and multi-axis parallel testing systems allow these solutions to be tailored to specific operational requirements.

Each item in the list links to a more detailed product page where you can find informational videos, supported ISO standards, and more detailed technical descriptions.

roboTest N: : a mobile robotic testing station for simpler testing applications and smaller series, designed for semi-automatic testing of lighter weight specimens. Typical applications include testing of autoinjectors, including cap removal, break loose force and glide force of up to 30 specimens. The roboTest N is also ideal for testing of Luer lock connectors.

[> View Solution](#)

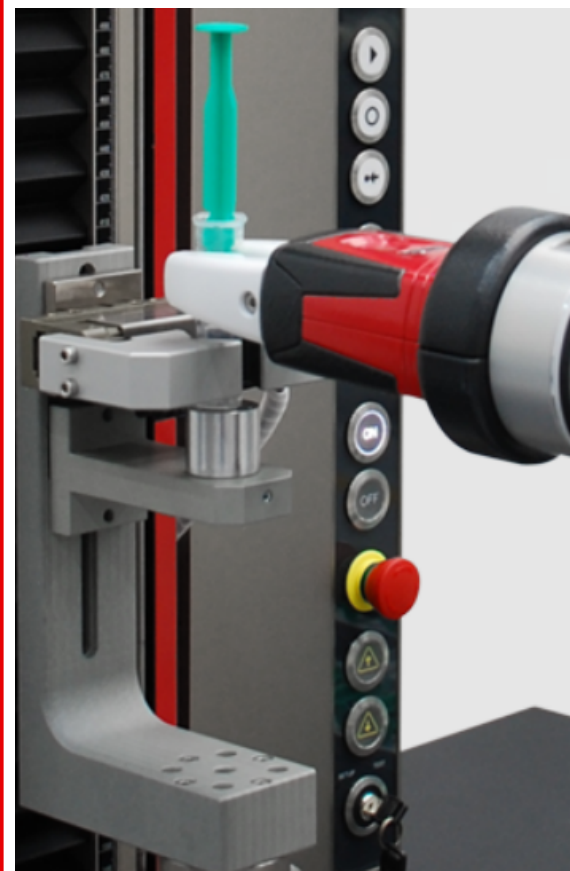
roboTest R: this system can support tensile, flexure, and compression testing, and is well suited for the complex testing tasks associated with autoinjectors and dosage pens.

[> View Solution](#)

roboTest N	roboTest R
Lightweight robot for simple tasks	Complex test tasks
Pick and place applications	Full automation of the complete test process
Small series (up to 30 specimens)	Large specimen volume (up to 400 specimens)
ISO 11040, ISO 11608-5, ISO 11608-6, ISO 80369	ISO 11040, ISO 11608-5, ISO 11608-6, ISO 80369
Autoinjectors, OBDS, Pen Injectors, syringes	Autoinjectors, OBDS, Pen Injectors, syringes
For testing machines up to 20 kN	For testing machines from 5kN to 2000 kN

Medical engineering puts a particular premium on reliable test results, making it a natural fit for ZwickRoell's automated testing solutions. Prototypical applications include testing of autoinjectors, dosage pens, and syringes.

Because ZwickRoell's automated testing systems utilize a modular and customizable design, they can be the perfect solution for more specialized applications—particularly for the unique needs of component testing.



Learning More About How ZwickRoell is Unlocking New Possibilities in Automated Material Testing

ZwickRoell is a global leader in materials testing and offers deep expertise on automated testing systems. We have delivered over 700 automated testing systems worldwide and deliver approximately 40 more every year. We take pride in our ability to match the right testing solution to each client's unique business requirements, providing tailored solutions backed by a long-term service and support partnership.

We carefully engineer every component in every testing solution, diligently evaluating the complex interactions between components. This meticulous approach is the only way to ensure the accurate, precise, reliable, repeatable test results that underpin success in all materials and components testing.

If you are interested in learning more about finding the right automated solution for your materials testing challenges, we encourage you to [reach out to our team](#).

[> Contact Form](#)

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