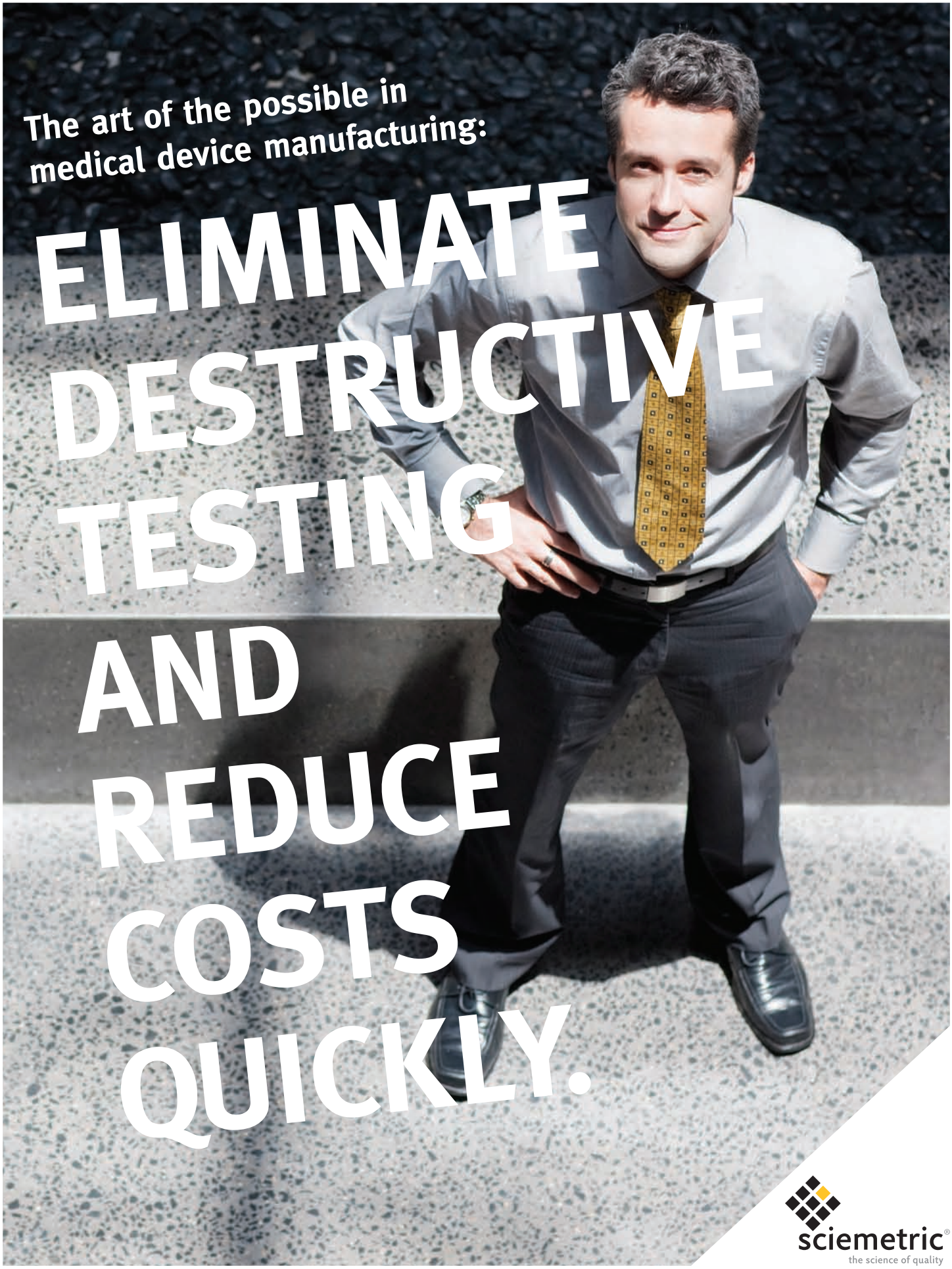

The art of the possible in medical device manufacturing:
ELIMINATE DESTRUCTIVE TESTING AND REDUCE COSTS QUICKLY.
sciemetric®
the science of quality

WE'VE CHANGED
THE RULES.
NOW IT'S YOUR
TURN TO DO
THE SAME.

More and more medical device manufacturers are discovering the benefits of implementing Sciemetric's unique process signature technology.

It's a proven alternative to subjective visual inspection or the wasteful and expensive end-of-line sample testing that's traditionally used for quality assurance.

**Sciemetric enables you to catch defects *when* and *where* they occur in production—in real time, not after the fact.**

Just as important, with Sciemetric integrated into your production line you can be confident that *your entire manufacturing process is documented*, with complete traceability of every component, for regulatory and standards compliance.

- Eliminate destructive testing and reduce costs quickly
- Optimize manufacturing processes to meet performance goals
- Accelerate time to market with quality you can prove

## THAT'S SCIEMETRIC FOR YOU.

# NOW, EVERY PRODUCT IS A BATCH OF 1

With traditional end-of-line testing, product quality is not established until an entire batch has gone through production and sample tests have been completed. In some cases, tests may be lengthy and take days or even weeks to complete. If defects are detected, the long delay between manufacturing and receiving test results can mean that other products—sometimes thousands of devices—have been manufactured with the same defective process or parts.

**Sciemetric's process signature technology empowers you to take a different, more efficient approach to ensuring quality.**

By analyzing process signatures and monitoring critical features in real time, the Sciemetric process identifies and rejects defective parts on the production line, before continuing to the next step. This allows parts to be removed as early as possible, improving the efficiency of manufacturing and reducing costs by ensuring that resources at subsequent steps are not wasted.

**If the ultimate goal is a better bottom line while providing safe, reliable, and affordable products to the health care industry and consumers, it's time to rethink how you measure, achieve, and *prove* quality in your manufacturing.**

# REDUCE COSTS IMMEDIATELY AND SEE FAST ROI WITH SCIEMETRIC. HERE'S HOW:

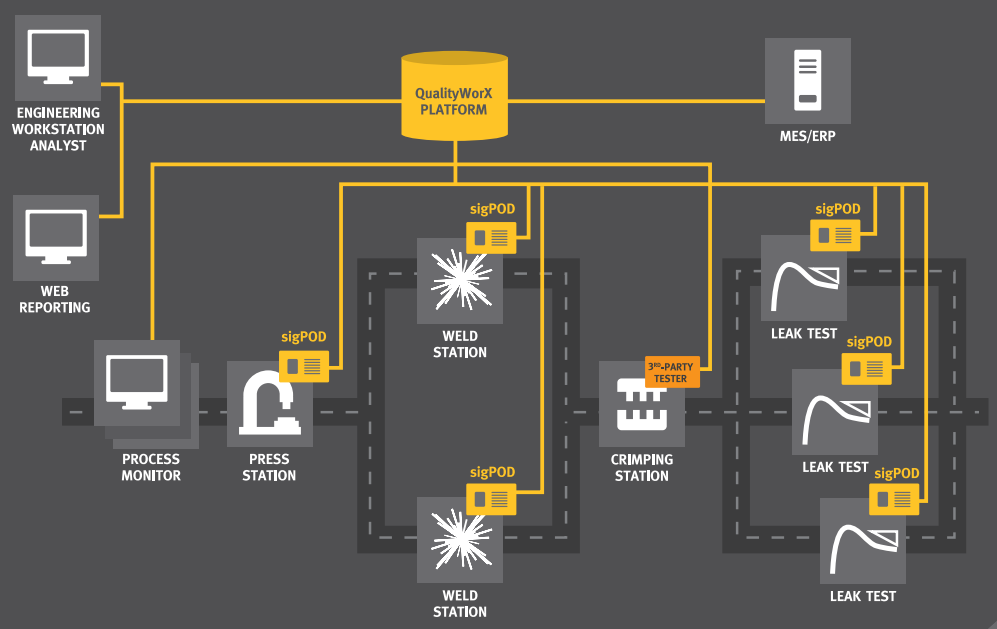
| DESTRUCTIVE TEST EXAMPLE | |
|---|---|
| **Unit cost of manufactured parts**<br>The cost to produce a single part on the production line | $0.80 |
| **Estimated annual production**<br>Approximate volume of parts produced annually | 2,750,000 |
| **Destructive test sample size**<br>The percentage of parts from a single batch sampled to demonstrate statistical quality assurance | 7.5%, or 206,250 units |
| **Cost of investment**<br>Approximate investment in Sciemetric process signature technology to eliminate destructive testing on a single line | $50,000 |

| ROI CALCULATION | |
|---|---|
| **Annual material savings** ($206,250 x $0.80) = | **$165,000** |
| **Time to payback in days** ($50,000/($165,000/365)) = | **111** |
| **Return on investment**<br>(($165,000 – $50,000/$50,000) x 100) = | **230%** |

The example above does not include capital or labour costs associated with the destructive tests themselves or costs incurred when a sample fails; e.g., the potential scrapping of an entire batch. Note the immediate cost savings by eliminating destructive testing. In most cases, this saving alone is enough to generate 100% payback within the first year, if not sooner. Over time, product costs should also decrease due to continuous improvements on the production line, leading to higher yields.

## SCIEMETRIC'S UNIQUE APPROACH

The **sigPOD**™ platform uses advanced process signature verification to monitor a wide range of manufacturing processes, delivering real-time feedback while collecting all process data. The **QualityWorX**® quality operating system archives the data from the production line, including process signatures, into a single database while providing the tools for easy reporting, traceability, and the ability to conduct detailed analysis for process improvements.



QUALITY
YOU CAN
PROVE

**As a medical device manufacturer, you know that shipping defective products is expensive. The cost of recalling devices and replacing them almost always exceeds the cost of the parts themselves. FDA sanctions can take an even higher toll, resulting in millions of dollars of lost revenue per day while you are unable to sell your products.**

**Applying process signature technology can give you complete confidence in your quality assurance methodologies.**

**With Sciemetric on your production line, you can:**

- Achieve 100% verification of devices against known failure modes
- Demonstrate the compliance of any individual device or group of products at any time
- Identify the cause of any quality spills quickly—within minutes, in fact—and address regulatory requirements to allow the release of your products back into the market in the shortest possible time

To learn more about Sciemetric and what our process signature technology can do for your business, read our white papers—including ***How to Eliminate Destructive Testing*** and ***How Medical Device Manufacturers Can Improve Quality by Applying the Principles of Process Analytical Technologies (PAT)***—or use the convenient ROI calculator at **www.sciemetric.com/medical**.

## ABOUT SCIEMETRIC

Sciemetric is the premier provider of process monitoring, analysis, and traceability solutions for manufacturers. We are shaping the future of efficient, high-quality manufacturing.

Our solutions deliver the insight that manufacturers require to improve quality, increase productivity, and decrease costs across the entire production lifecycle.

Sciemetric pioneered Process Signature Verification for manufacturing in the 1990s and our customers are leading manufacturing companies in the automotive, industrial, medical, electronics, and other sectors around the globe.

**Contact us for an assessment of your production line**
Let us help you achieve your quality and productivity objectives.

Call toll-free in North America: 1-877-931-9200
Visit our Web site for international contact information.
Email: inquiries@sciemetric.com

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