



How to Eliminate Destructive Testing

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Historically, medical products have been manufactured in batches or lots, with a sample of the devices subjected to destructive, visual or audit testing to evaluate quality.

More recently, however, a paradigm shift has begun to take hold in medical device manufacturing, enabled by advances in measurement and data management technologies. The result is a movement away from end-of-line sample testing and towards the adoption of in-process measurement strategies that ensure product quality in real-time, on a part-by-part basis. This in-process strategy is based on the principle that all manufacturing defects are the result of deviations in one or more process inputs, including variations in component characteristics, process station parameters or environmental factors. Therefore, by collecting and analysing data on all of the critical inputs throughout the manufacturing process, it becomes possible to control and ensure product quality far more effectively than with the traditional approach based on statistically applied sample testing.

Central to this new approach is the introduction of process signature analysis to all critical manufacturing steps. By analyzing the data gathered on all of the relevant process inputs, it is possible to develop a detailed understanding of the underlying physical processes, and how these process variables interact to affect product quality. This approach provides a number of key benefits to both the manufacturer and the consumer, many of which seem almost contradictory in nature: reduced product costs and improved manufacturing efficiency, while simultaneously generating significant improvements in product quality, traceability, and risk mitigation.

The Traditional Approach – Sample Testing

As mentioned above, the traditional approach to ensuring product quality is based on testing a statistically representative sample of parts from each production batch. The tests are designed to evaluate whether the samples meet the product requirements, both from a function and performance perspective, as well as for reliability and durability. In many cases, these parts are destroyed during the course of the test. Based on the results of these sample tests, the failure rate of the remaining parts is statistically estimated. If the estimated failure rate is above acceptable limits, the entire batch is removed from production, quarantined and, in many cases, scrapped. This approach is illustrated by the flow-chart in *Figure 1* below.

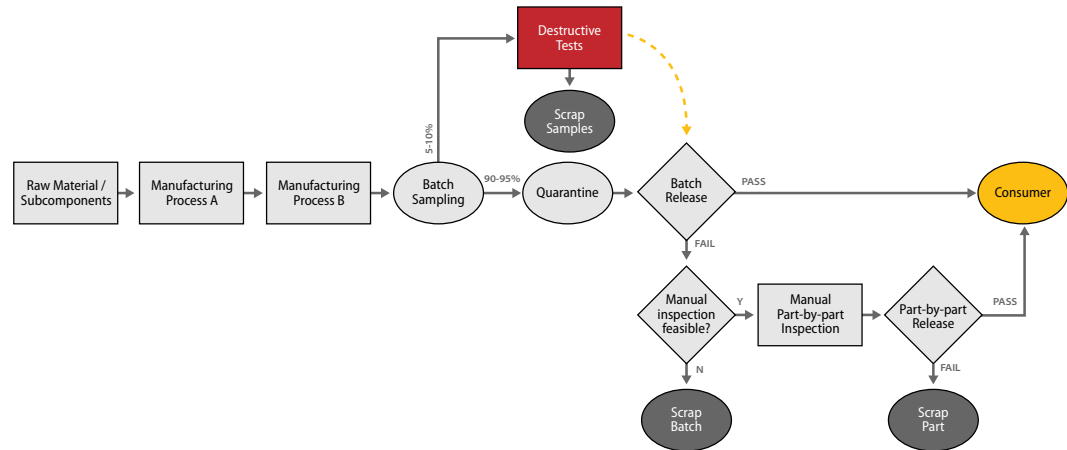


Figure 1: Flow chart showing traditional approach of batch-based destructive testing

The effectiveness of this approach relies strongly on how well the process is controlled, as it is assumed that the failure rate of the test sample is representative of the entire lot. The less controlled the process, the larger the required sample size, and the higher the cost of the testing. This includes the labor and capital costs associated with the performance of the test, as well as the cost of the sample parts that are destroyed in the test, the vast majority of which are perfectly good. As a result, maintaining a well-controlled process is critical to controlling costs. Unfortunately, without a means of directly monitoring the performance of the manufacturing process, maintaining control often means relying on regular and effective maintenance and strict adherence to procedures and protocols.

There are several key limitations to the sampling approach. First of all, it provides little or no direct evidence of product quality for the parts that are actually shipped to the customers. Rather, there is the assumption that because other parts manufactured in the same lot met all requirements, the remainder of the parts would be of the same quality. Second, in many cases the tests that are applied to determine product quality generally result in the destruction of the samples. This means that the overall yield of the batch or lot is instantly reduced by an amount equal to the size of the test sample. Furthermore, if the sample fails, the manufacturer must either institute an expensive part-by-part manual inspection of the batch or, if this is not feasible, reject the entire batch, even if 90 or 95% of them are of good quality. This is necessary to prevent the 5 or 10% of parts that are of poor quality from being shipped to the customer, since there is no way to identify the good parts

from the bad ones. Finally, with end-of-line testing, product quality is not established until the entire batch is through manufacturing, and the sample tests have been completed. In some cases, the tests may be lengthy and take days or even weeks to complete. If defects are detected, the long delay between when the product was manufactured and when the results were obtained can mean that several other batches, and perhaps thousands of devices, have been manufactured with the same defective process parameters and will also need to be quarantined.

The New Technology: Process Signature Analysis

The alternative to destructive sample testing upon completion of the manufacturing is to collect data *during* the critical processes. This represents a fundamentally different approach to managing risk and instills quality directly into the manufacturing process. Instead of extrapolating quality attributes from statistical batch sample data, each and every part is evaluated individually, increasing the test coverage to 100%. Furthermore, since data acquired in-situ during manufacturing can be correlated to the precise step where the defect was created, it provides valuable feedback for optimizing and maintaining the manufacturing processes. This ensures that the quality of the manufactured product is controlled and maintained on a continuous, on-going basis. Finally, by consolidating and storing all of the in-process test data associated with each part, it becomes a vital component of the device history record.

The key to this approach is to develop a test methodology that can detect defects as they are being formed during the manufacturing process. The most accurate approach involves monitoring and recording key attributes in real time throughout the duration of the process. This produces what is called a “process signature”: a characteristic curve whose shape contains detailed information about the quality of the manufacturing process for each individual part, much like an ECG reveals insight into the health of a beating heart. By recording and analyzing these process signatures, it is possible to identify key features in the signatures that are correlated with final product quality. These features can then be tracked and tested against limits to determine pass/fail on a part-by-part basis. *Figure 2* below shows a generic illustration of a process signature, including a variety of features that can be extracted from the curve.

**... each and every
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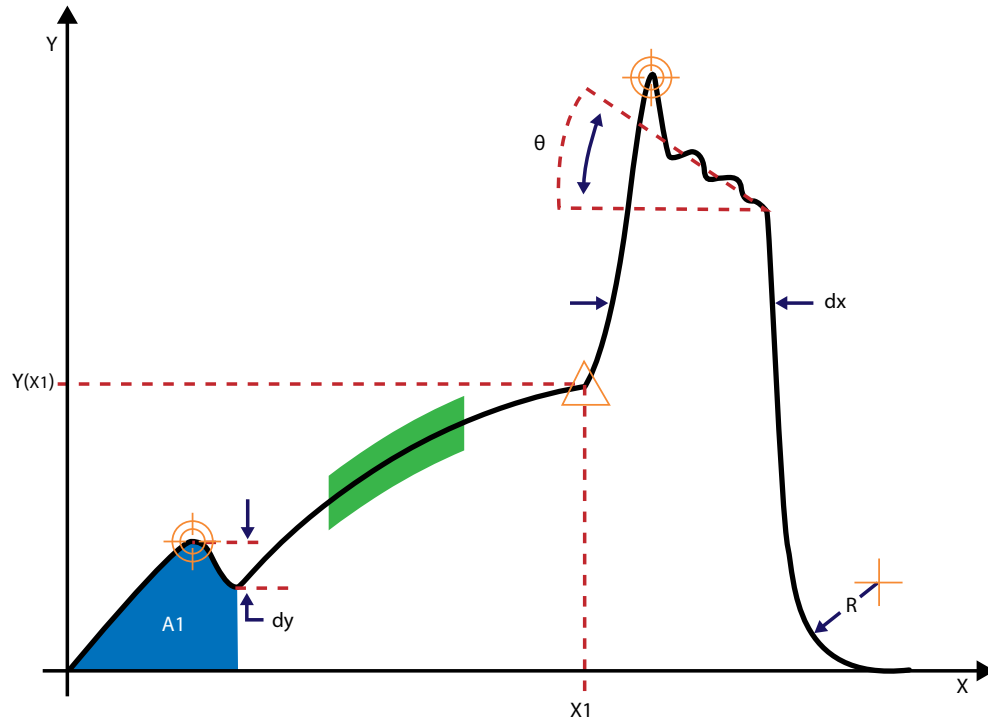


Figure 2: Illustration of a process signature showing examples of different feature types that can be extracted and monitored in real-time.

To implement this new approach requires a measurement technology that can capture process signatures in real-time with the accuracy and resolution necessary to detect the differences between good and bad parts, even when the differences are subtle. This approach has been in use for decades in the electronics domain, where sampling oscilloscopes are commonly used to measure, display and analyze electrical waveforms. With high resolution sampling technologies that can capture more than 1 million samples per second, it is now possible to monitor just about any characteristic or parameter in a similar manner during the manufacturing process. The other critical component is a set of data analysis tools that can be used to analyse and extract key features from the process signatures. Ideally this would be combined with a database for storing both the features and the signatures, which would enable the rapid correlation of process data and product quality attributes. Finally, the availability of inexpensive process monitors with ample processing power and data storage makes it practical to deploy these types of monitoring solutions throughout the manufacturing line.

Implementing Process Signature Analysis

The first step in implementing an in-process test methodology is identifying the critical steps in the manufacturing processes. This should be based on a scientific understanding of the underlying physical processes and the overall end product requirements, which include performance, functionality and reliability. For each of the critical processes, one must identify which parameters should be monitored to produce the process signatures that will provide the best indicators of product quality. Again, this should be based on a scientific understanding of the process and the root causes of any known defect modes.

The next step is to correlate the process signatures with the relevant product quality attributes. The most effective approach is to run a design of experiments (DOE) where all of the key process variables are systematically varied across the range of acceptable bounds. All of the parts are then subjected to end-of-line tests to evaluate the impact of these changes on final product quality. These tests may include functional or performance tests, visual inspections, destructive tests, or accelerated stress tests. Meanwhile, the process signatures obtained from the in-process tests can be overlaid and compared, to reveal key features that are correlated with final product quality. Examples of features that can be extracted from the process signatures include minimum or maximum values, slopes or curvatures, peak frequencies, or areas under the curve.

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This analysis provides the basis for the in-line production tests: by analyzing the process signatures and monitoring the critical features in real-time, defective parts are identified and rejected on the production line, before continuing on to the next step. This provides the advantage of detecting defects as they are being formed, allowing defective parts to be removed from the process as early as possible. This improves the efficiency of the manufacturing line, since resources at subsequent steps are not wasted on parts that are already defective. Furthermore, the in-process data provides critical feedback that can be used to control and optimize the manufacturing processes during production. This is illustrated in *Figure 3*, where a simple example of a two-step manufacturing process is shown.

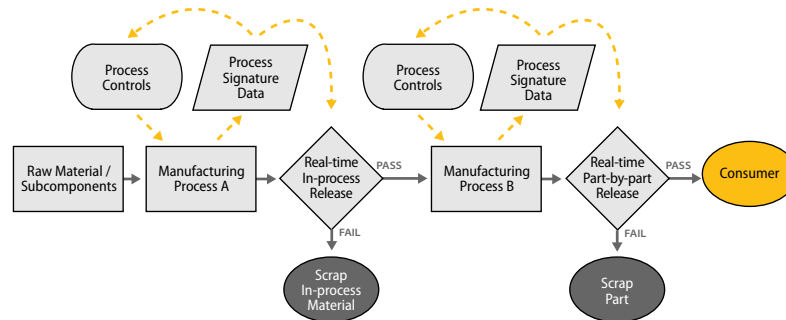


Figure 3: Flow chart showing real-time release process based on process signature analysis.

Eliminating Destructive Testing

Once the in-process tests results have been validated against the destructive end-of-line tests, it is possible to eliminate them without any loss of product quality. Instead, quality is guaranteed by monitoring, analyzing and recording the in-process data on *each and every part* as it is being manufactured. This represents a profound change in the way product quality is controlled. The end results are significant cost savings both immediately and in the longer term.

The immediate cost savings come from the elimination of the destructive tests themselves. No longer is it necessary to destroy 5 or 10% of the manufactured parts, the vast majority of which are perfectly good and meet all requirements.. In most cases, this cost savings alone is enough to generate 100% payback within the first year, if not sooner. This is illustrated by the example shown in *Table 1*, where payback takes less than 4 months, even for a low value part where the manufacturing cost is less than a dollar; this would occur even faster for a higher value part such as a pacemaker. In addition, the cost of running the tests themselves, which can often be time-consuming and therefore expensive to perform, is also eliminated. Capital requirements may also be reduced, since the tests will only be needed for validation purposes and not on the production line itself. Altogether these costs can be extensive, particularly when the value of the product is high.

Over time, product costs should also decrease due to continuous improvements on the production line, leading to higher yields. This is accomplished by optimizing and

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controlling all of the critical manufacturing processes based on the real-time feedback provided by the process signature data. SPC analysis can now be based on individual parts, instead of batch-based data, providing more accurate statistics and more rapid feedback. In essence, this is equivalent to reducing the batch size from thousands down to one. This enables process drift to be minimized and hence variations in production yields will also be reduced. The occurrence of the “bad batch” should essentially disappear.

DESTRUCTIVE TEST EXAMPLE

| | |
|--|------------------|
| Unit Cost of Manufactured Parts | \$0.80 |
| The cost to produce a single part on the manufacturing line. | |
| Estimated Annual Production | 2,750,000 |
| Approximate volume of parts produced on an annual basis. | |
| Destructive Test Sample Size | 7.5% |
| The percentage of parts from a single batch that must be sampled to demonstrate statistical quality assurance. | |
| Cost of Investment | \$50,000 |
| Investment in Process Signature technology required to eliminate destructive testing on a single line. | |

ROI CALCULATION

Annual Material Savings = \$165,000

Time to Payback (days) = 111

Process Signature ROI = 230%

Table 1: Table illustrating the cost savings associated with the elimination of destructive testing attributed to the value of the sample parts alone. This does not include capital or labor costs associated with the destructive tests themselves, or costs that are incurred when a sample fails the destructive tests, eg. the potential scrapping of the entire batch.

Finally, the fundamental shift away from end-of-line sampling to 100% in-process testing ensures a higher level of product quality, which in the long run is guaranteed to save the manufacturer money. With the sampling approach, the manufacturer relies on statistics to infer the quality of shipped product based on the results obtained from a small sample of parts from the same lot. This really only estimates the probability of encountering a defect, and does not ensure that none are shipped. In fact, it is virtually guaranteed that defective material *will* be shipped, it is simply a question of “how much?” With in-process testing, critical data is collected on each and every part, enabling the manufacturer to verify that each shipped part is defect-free.

This last point is critical because, quite simply, *shipping defective product is expensive*. The cost of providing replacements almost always exceeds the cost of the part itself: managing the replacement process, lost business due to a perception of poor quality, all contribute to the added cost of dealing with field failures. However, the largest costs can be incurred when the scope and impact of product failures leads to lawsuits or FDA sanctions. Recent class action lawsuits for medical device manufacturers have resulted in settlements in the hundreds of millions of dollars, which is on top of the legal costs incurred in defending the company against the suits. FDA sanctions can be even more costly, resulting in millions of dollars in lost revenue *per day* while the company is unable to sell its product or products. Clearly the importance of avoiding these situations cannot be understated.

In addition, by capturing and storing the critical in-process data, a comprehensive test record for each shipped part is created. This can be integrated into the manufacturer's quality systems to become an important part of the device history record. This provides protection for both the consumer and the manufacturer, since the critical attributes of each part are recorded and stored for examination should the need arise. For example, in the rare event that a new failure mode is discovered, having the process signature stored and available for analysis can provide tremendous value. By re-examining the process signatures of the known failures, and identifying features associated with the new defect, it is possible to reanalyze the recorded signatures for the entire population of shipped devices, and identify any other similar failures. This can dramatically reduce the scope of any product recalls, and thus limit the exposure due to associated lawsuits or FDA sanctions.

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| | DESTRUCTIVE TESTING | REAL-TIME RELEASE |
|---|--|--|
| Test Sample Size | Typically 5-10% of population | 100% |
| Maximum Possible Yield | 90-95% (assuming sample size of 5-10% – depends on test sample size) | 100% |
| Cycle Time for Closed Loop Control | Sum of lot processing time and duration of end-of-line destructive tests. Tests may add hours to days beyond batch manufacturing process time. | Determined primarily by single part processing time, with little or no additional time to collect and analyze the process signature data. |
| Test Costs | Includes off-line test stations, test labor, fixtures to evaluate functional, performance, and reliability characteristics. | No additional test stations or test labor required – collected in-situ during manufacturing process. May require addition of sensors and data acquisition hardware to collect critical process signatures. |
| Test Coverage of Shipped Product | 0% - extrapolated from sample on a batch basis | 100% - each part tested and evaluated individually |
| Device History Record | Primarily batch-based test data. Part-specific data potentially available on subcomponents, environmental conditions. | Process signatures can be collected and stored on part-by-part basis, in addition to part-specific data potentially available on subcomponents, environmental conditions |

Table 2: Comparison of end-of-line destructive testing and real-time release

Conclusion

With the introduction of process signature analysis technologies, more and more manufacturers are moving away from the traditional sample-testing approach to a real-time release system where each part is evaluated individually, based on its process signatures. This allows the manufacturer to significantly reduce product costs, both by eliminating destructive testing and by improving manufacturing yields and efficiencies. What is perhaps most impressive is that these savings are achieved at the same time that it delivers improved product quality through 100% screening, and reduced risk by providing a more detailed device history record. In the end, the combined advantages of a more cost effective, higher quality product can provide the competitive edge necessary to succeed in today's competitive medical devices market.

**If you'd like to eliminate destructive testing, reduce costs and improve quality,
contact us.**

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