Introduction

This presentation describes the science of Process Signature Verification™ (PSV), developed by Sciemetric Instruments Inc., and its role in the assembly manufacturing environment.

Review the notes beneath each slide for additional information and explanation of the slide content. Please forward any questions by email to inquiries@sciemetric.com.
Device Manufacturing

- Market undergoing paradigm shift
  - Risk Management pushed into manufacturing ISO 14971
  - PAT and GHTF Guidance
- Manufacturing looking to automotive
  - Moving from batch to single part flow systems
  - Higher volume manufacturing
  - Decreasing margins
- 3 significant pain-points we can help with.

The environment around the manufacturing of medical devices is changing for two reasons:

The first is regulatory. The FDA, as well as the European, Canadian and Japanese regulators have done two things: request risk management in production processes and allow for enhanced in-process verification.

The second is the increasing volume and decreasing margins associated with many medical devices. Plant floor issues are becoming more like those of other manufacturers – except with more critical quality requirements.

Medical device manufacturers are starting to look to gain from the experience of high volume, high complexity manufacturing environments for tools and techniques to assist in controlling product and process variability.

Signature analysis is one such tool. It has been used effectively for 15 years to find defects and speed up manufacturing line commissioning, and to provide high quality data and tools for root cause analysis.
Process Signature Verification brings true process understanding and evaluation onto the manufacturing floor. This science can help achieve compliance manufacturing processes, shorten the validation and of manufacturing lines, and propel increases in both yield and quality.

If we take a look at the FDA’s view of process understanding:

We can use inspection to measure end quality and reject lots, but cannot always determine root cause and prevent recurrence. Conventional testing doesn’t provide enough information and in some cases is not evaluating all of the CTQs in a product. Process understanding is needed.

Process Signature Verification is based on the concept of Process Signatures.
Every Process Has a Unique Signature

Like every beating heart:

- ‘Features’ within this signature tell you about the process.
- Did the process go well; did it vary, have failure modes or defects been introduced?

For instance: this slope tells me if two parts are fitting too loosely together.

Every manufacturing process has a unique parametric signature that can be used to determine the success or failure of that process.

An electrocardiogram (ECG) provides a very close analogy as it is a process signature. The process is the beat of a heart, the exercise of a fluid pump. The output of a heartbeat is blood flow through the body.

The ECG does not measure the blood flow directly, but measures a critical parameter, the electrical response of the heart, to determine whether the output is correct. To the untrained eye, two individual ECG signatures will look similar, perhaps identical. But the heart specialist EXTRACTS certain key FEATURES from this complex signature to pinpoint issues and “non-compliance.”

Exactly the same thing can be done with a process or test. Key FEATURES of the curve and the curve itself are extracted on-line to identify a compliant or non-compliant process. We evaluate the response of a critical parameter to determine whether that process is correct and the part is good.
The Process Signature allows us to achieve “process understanding” and to transport that from the lab to the manufacturing floor.

In the laboratory our analysis tool gives you the power to make sense of thousands of research signatures effortlessly. Extract features that indicate failure modes or non-compliance. The features you extract from your curves as you characterize your process are used identically on the manufacturing line, for 100% scientifically-based verification of compliance and, simply, the best defect detection possible.

The intelligence provided by your best quality process development engineers is transported real-time on the manufacturing line.

The software code is the same in both environments (lab and plant floor) and is validated.
Process Signatures allow a manufacturer to do three important things that cost-effectively provide continuous improvement:

1. 'See' into your process behavior
2. Create a 'gold standard'
3. Pinpoint difficult-to-detect variations

The following slides describe each of these.
To understand how we can ‘see into’ process behavior we need to start with what today’s SPC permits.

SPC process monitoring is typically very well executed; the parameters are well chosen, the limits are correctly and sensibly set and every part is monitored for a test.

The difficulty with SPC is not the usage, but the nature of the information. Only two points are used to infer a ‘curve’.

In one real-world example, a part under vacuum was regularly passing the production test, but 18% of passed parts were failing downstream.

The next page tells you what we uncovered.
A quick glance at the full process signature shows that even though the parts passed the SPC monitoring, many of them are not in compliance with expectations. These parts have anomalous, unacceptable behavior, which lead directly to the downstream issue.

Based on the signature information, the root cause of the failure was identified as a faulty component. The part was redesigned and replaced, removing the downstream failure issue.

When you track the ENTIRE signature from your process this visibility of process detail will help you identify and resolve manufacturing issues. A manufacturing process that is in compliance with its specification is very repeatable. If it varies, the resulting parts are not the same.
Create a ‘gold standard’

A data-derived specification for a well-behaved process

Empirical way to generate a specification for a well-behaved process. So now you have a standard for:
- process verification
- proof of compliance
- faster validation
- control operations

In the lion’s share of manufacturing processes, it is not possible to develop a model of behavior from pure theory. Process Signature monitoring provides a way to create an empirical statistical template of a process. In other words you can learn the specification for the well-behaved process. That specification is the gold standard signature.

These signatures need to be discovered through experimentation. Sciemetric gives manufacturers the tools to ‘discover’ the specification.

This specification or standard can then be used on the production line to allow verification of even extremely complex processes or operations.
Pinpoint difficult-to-detect variations

1. Use detailed, Signature-specific mathematical modeling

2. Find subtle indications of process failure that allow you to determine the ‘root cause’ of problems

The red curve looks compliant before processing. Mathematical algorithms isolate out-of-tolerance behavior.

Detailed mathematical modelling algorithms allow you to detect very subtle indications of process variation that induce defects—defects that you were previously unable to see.

In the image above there is a bright red line in the center of the upper curves which looks like it is easily within statistical acceptability. However, reviewing this with mathematical tools it is clearly non-compliant with the bulk of the curves, an effect you would not see from the un-processed curves.
How does Process Signature Verification (PSV) work?

1. Applicability is limited only by sensor technology; so long as there is a sensor that can convert the critical physical parameters into electrical signals then Sciemetric’s proprietary Process Signature Verification can do the rest. This is why we work with a wide variety of sensor manufacturers.

2. Next, we digitize the sensor signal at very high speed – up to a quarter of a million data sample points per second. From this we generate a waveform or signature. Sciemetric’s SigPOD test system is designed specifically for this purpose.

3. We then analyze this signature using our built-in math tools to maximise the difference between “good” and “bad” signatures. The pre-processing algorithms include FFT, derivative, filters, etc. Then we FEATURE EXTRACT, just like the ECG specialist we mentioned earlier, so that we now are able to “describe” a good and bad part or process.

4. This then allows us to control quality in the manufacturing line by passing and failing in real-time against the extracted feature set.

5. Our off-line software technology, QualityWorX, allows the manufacturer to turn this data into information into actions, facilitating continuous improvement.

All of this enables the improvement of both yield and quality, so often mutually exclusive in the manufacturing arena.
In terms of operational components, Sciemetric provides the following:

- **Data acquisition and verification systems** collect data at high speed and provide industry-leading A-D conversion. The signatures collected are then analyzed for behavior that will indicate defects. A pass or fail is issued.

- **Test record database**: Every signature and calculated measurement is packaged in a test record and stored in a database.

- Our **workstation tools** allow analysis on hundreds of test records simultaneously. In these tools the algorithms that detect very specific and individualized failure modes within your processes are evolved.

- Finally, these algorithms are installed back in the data acquisition and verification systems to detect precisely the signature behavior that isolates the failure mode or characteristics you seek.

This loop can be repeated at your discretion as you optimize your process.
The following four slides review the impact of process signature verification on manufacturing operations.
Sciometric has a chart of over 50 identified process and tests that are easily accessible through the monitoring of physical parameters. In essence, with the advance of sensor technology, anything that you can see, feel, or hear can be measured. For example:

- Process elements that can be measured by “feel” include profiling, temperature force-related operations such as bending etc. and the receipt of electrical signals.

- Sound can be used to measure quality of powder formed, cast, and forged, pressed, and bonded components for the detection of cracks, de-lamination, and porosity and de-bonds.

While there are many different manufacturing types, our experience is that most of them contain standard physical operations, such as squeezing or pushing something, bending it, welding it, melting it, fastening it, gluing it, polishing it or grinding it.
View tool behavior as well

- Curves from a ‘pull and release’ operation on a polymer
  - Material: we can clearly see the force effect of heating
  - Tooling: We also see unexpected evidence of slippage (green signature)
  - Tooling: friction in servo motor assembly (furry lines)

Signature analysis and verification will not only give you information about your materials and process, but about the tooling as well.

In the green curve, for instance, we see evidence of a part slipping form the tooling, even though this slippage was not visible to the naked eye. There is also clear evidence that the servo motor is generating more friction than is desired. We can see this friction because we are measuring about 1,500 points a second in this study. Measurements up to 150 KHz are available.
Manage variability plant-wide

Analyze test records based on plant-wide inputs:

- Machine number
- Alternate materials
- Build recipe/model types
- Batch
- Part history
- Component vendor

Key inputs to variability to product quality can truly be measured and tracked—easily. Plant-wide inputs which could not previously be analyzed on a daily basis are directly accessible to quality staff.

One of the big challenges in medical device manufacturing is that processes are developed in a very static way: one material, one defined set of constraints with a small process window.

When the real world causes problems, such as being forced to use a different vendor’s material, you often do not know where the true sensitivities are in a process and it is very difficult to adjust. When detailed process understanding is available throughout the plant environment, adjustment can be made with more control and predictability.
Impact on Manufacturing Operations

- **Yield and Quality**
  - Instantaneous picture of process – “Process Insight”
    - Determine root cause of variability – “Defect Avoidance”
    - Fast corrective action based on process understanding
  - Scientific limit setting and maintenance scheduling
    - Optimal limits for the process or part
    - Reduced false failures
    - Accurate maintenance timing vs. historical schedule
  - Replace human subjectivity with scientific objectivity
    - Process improvements driven by scientific facts
    - Scientific, data-determined pass/fail

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Process Signature Verification offers the chance to change the relationship between yield and quality. It is generally easy to raise yield by forgoing quality, or raise quality at the expense of yield. PSV offers you the opportunity to increase productivity by linking yield and quality increases.
Following are examples of the value PSV delivered in customer applications.
Reduced Recalls

Detailed data allows for analysis even after shipment

- Unexpected failure happens in deployed device
- Root cause of failure determined through analysis of historical data
- Defect isolated to exact parts, allowing pin-point recall
- Sciemetric reduced recall by from 10,000 to 7 units
- Detection programmed into online units for continuous monitoring

The cost savings realized by the manufacturer by being able to pinpoint the cause of the issue were great. The quarantine on the affected line was short-lived, meaning that the impact on production was minimized. The costs of the warranty were also much reduced. But, importantly, the manufacturer avoided negative publicity, which can impact reputation and future sales.
Improved Gage R&R

High confidence allows accurate tests on sensitive parts

- Gage Repeatability (instrument variation) and Reproducibility (tool & operator variation)
- Instrument variation is decreased significantly
- With decreasing instrument variation the overall variation improves.

Decreased variability 50% for leading ink-jet cartridge manufacturer

Sciemetric offers two things that improve Gage R&R. The first is high speed and high resolution data.

High speed, high resolution data means your signature can pick up very small defects more reliably. This is related to the Nyquist sampling theorem that states that you must sample at ‘at least’ twice the rate of change to confidently detect small changes.

Sophisticated math tools allow you to preprocess the data to both remove extraneous signals and enhance the areas of interest before measurements of a specific curve feature are made. This isolates and improves the areas of interest giving you a much more repeatable test.
Improved Visibility Enterprise-wide

Integrate analysis and manufacturing skills company-wide

- Resolve quality questions around the world immediately
- Debug processes and analyze failure modes on remote data
- Disseminate experience to new and changing sites
- Model process controls and yield curves off-line for any site

Line launch accelerated by 400% for major multi-billion-dollar manufacturer.

The application of PSV throughout the enterprise enables sharing of information and meeting the goal of consistent product quality, regardless of where it is being manufactured. New production lines can be launched more quickly and efficiently leveraging knowledge and skills from across the organization.
The final two slides provide a brief overview of Sciemetric Instruments Inc.

For more information, please visit our Web site at www.sciemetric.com.
About Sciemetric

Sciemetric has been around for more than 25 years and is a leader in manufacturing defect detection and defect avoidance technology.

Approximately 10 years ago now, we worked with Ford at the Windsor Engine Plant in Ontario to help this plant become the World’s first engine plant to eliminate the requirement to Hot Test every engine manufactured.

*Hot Testing is a term used to describe a test when an engine is actually started at the end of the assembly line as the final qualitative verification process – with gasoline and fumes and so on - expensive both in terms of cash and cycle time, emissions, safety, and other).*

We replaced this with a Cold Test strategy incorporating In-Process Verification at every major value-adding stage in the assembly process and an end of line cold test stand.

A Cold Test is where the assembled engine’s crank is turned by an electric motor and all key parameters are measured and analysed for performance and build quality – mechanical, fuel & ignition)

Ford was the World’s first auto manufacturer to enact this strategy and Sciemetric is proud to have been their test system partner.

All auto manufacturers are following this lead, and this is now the recognised standard method for quality verification in the industry.
**Our Experience**

We have worked with best-in-class manufacturers worldwide on a broad range of applications. Visit our Web site at www.sciemetric.com for application notes, detailed client list, product information and more.