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MEDICAL MANUFACTURING TECHNOLOGIES

GLEBAR
An MMT Company

Comparative Evaluation of Technology and Performance

The Glebar P5K Gauging System
vs. The Legacy P4K Gauging System

Abstract

The purpose of this White Paper is to compare the performance of the Glebar P5K Gauging System with that of the legacy Glebar P4K Gauging System. This analysis demonstrates that the P5K provides significantly more data due to its design, featuring 16,000 diameter readings per second.

As a result, the P5K **can produce 4x the data** while operating **at 4x the speed (sp) of the P4K.**

Process

In the Gauge R&R study, ten wires were produced using the Glebar Cam.2 Micro Grinder to create a representative sample that covers the entire tolerance range. The wires were designed to test various common features of guidewires, including:

• Paddles • Short Tapers • Long Shallow Tapers

To complete the Gauge R&R sample set, all ten sample wires were scanned three times by three different operators. An Analysis of Variance (ANOVA) test was conducted using Minitab as the basis for the study.

The Gauge R&R was performed on the P4K at 4 sp to establish a baseline, and the test was subsequently repeated on the P5K at both 4 sp and 16 sp.

When evaluating a Gauge R&R, the goal is to establish the source of any errors. Source errors that are statistically evaluated are:

• Product Variation • Operator Variation • Gauge Error

For this analysis, we will use product variation as the main metric. A high product variation, close to 100 percent, indicates that operator influence and any errors in the gauge itself are minimal. If multiple operators scan the same part several times, the results will be highly repeatable.

We will also evaluate the impact of remaining user and gauge influences in relation to physical measurements and the percentage of typical feature tolerances.

Key Features:

- **Diameter Accuracy:** +/- 0.5µm (0.00002")
- **Diameter Repeatability:** +/- 0.03µm (0.000001")
- **Motor:** ultra-smooth linear motor with 0.1µm (0.000004") resolution
- **Data Rate:** 40" (1m) of measurement travel in a single scan; high-speed, hard real-time data acquisition at 160kHz
- **Scan Rate:** up to 9" (225mm) per second

To learn more about the P5K, including a comprehensive list of features and specifications, please visit:

Speed

The speed of both the P5K and P4K is determined by the legacy drive parameter. Although this is not relevant to the current architecture, this decision was made for historical validation and training purposes. Four (4) sp is a typical scanning speed that is recommended for capturing high tolerance featuring like paddles.

- 4 sp = 19.2mm/s resulting in the 700mm scan taking **36.8 seconds**
- 16 sp = 76.8mm/s resulting in the 700mm scan taking **9.2 seconds**

Results

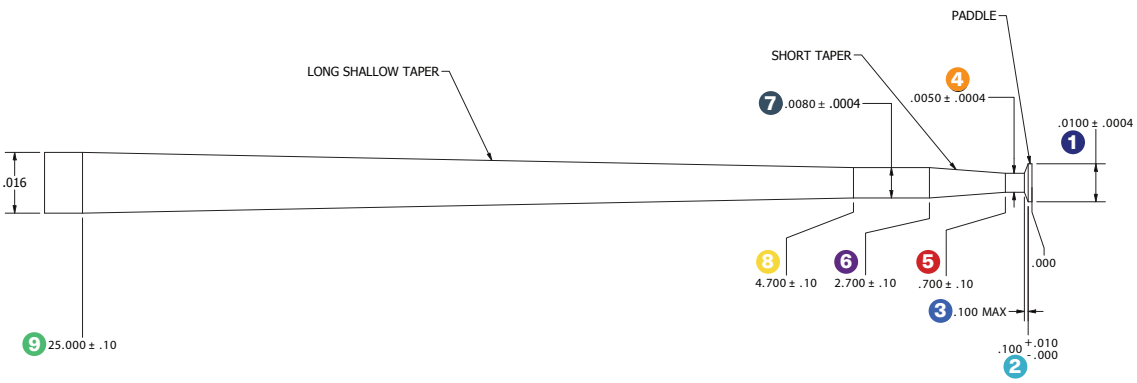


Image Description: Guidewire Paddle, Standard Length, and Shallow Tapers

Both the P4K and the P5K, at both speed settings, measured the diameters (1, 4, 7) at a rate greater than 99 percent product variation, better than 0.000 012” or 2 percent of a .000 4” tolerance zone.

On the paddle, length (2) showed similarly equal rules at greater than 98 percent across all speeds with a gauge attributed standard deviation of 0.000 5” or 5 percent of the 0.010” tolerance on both the P4K and P5K.

On the standard-length tapers (5, 6), the P4K recorded in the 98 percent range with the gauge attributed standard deviation at an average of .006”or 3 percent tolerance. The P5K at both speeds surpassed the P4K at a product variance of 99 percent with .003” std, or 1.6 percent tolerance at 4 sp and .004”, or 2 percent tolerance at 16 sp.

On long, shallow tapers (8, 9), the P4K averaged 93 percent product variance with a .025” std calculated or 12.6 percent of tolerance. On the P5K, both speeds averaged better than 95 percent product variance, with standard deviations reported of .013”, or 6.5 percent of tolerance.

Conclusion

The Gauge R&R testing confirmed that both the P5K and P4K are statistically proven as first-class gauging systems. However, **the P5K clearly excels in speed, making it the superior choice for efficiency.**

In terms of diameter readings, the P5K matches the P4K's performance seamlessly, independent of speed. Yet, when it comes to length measurement, **the P5K's enhanced data rate enables it to perform equally well or even surpass the P4K, even at 4x the speed.**

Product Information

MMT’s Glebar P5K Gauging System is the fastest, most accurate solution for medical guidewire measurement on the market. Measurement with the P5K is fully automated, ensuring **complete objectivity** and guaranteeing reliable results every time. Additionally, the frictionless air bearing motion provides **longer life** and **reduced maintenance** as mechanical wear parts are eliminated.

Built with the operator in mind, the **P5K delivers an enhanced ergonomic design, featuring standing, seated, and sit/stand options.** This sets the stage for unparalleled flexibility to improve operator comfort and productivity.

Other Features Include:

- Increased speed allows operators to significantly eenhance in-process quality control (QC) and return to the grinder more efficiently, and boosting overall productivity.
- The Reverse Engineering function permits Geometry Extraction from a scanned wire. This feature accelerates the creation of “to print” geometry saving extensive manual entry.
- The Recipe Wizard function delivers autogenerated recipes from geometry and tolerances. The software follows best practices for recipe programming, significantly lowering the training barrier.
- Accelerated, simplified Reporting allows for customizable default templates and batch processing.
- Reduced time required to establish a new product recipe, resulting in accelerated deployment while reducing the training required for personnel.
- Improved Traceability provides thumb printing, linking individual scans to the version of the recipe they were originally proceed against.
- Simplified recipe generation, updated geometry extraction, and real-time predictive analytics.

The NextGen Sensor and Software Updates Provide:

- More than 10x data capture rate (scanning 16,000 diameter readings per second)
- Automatic measurement, free of any operator influence
- Diameter and length reading every 30 millionths of an inch
- 4x scan rate (in comparison to the P4K)
- 2x repeatability

To learn more about the P5K, including a comprehensive list of key features and specifications, please visit:

mmt-inc.com/p5k-gauging-machine/

References

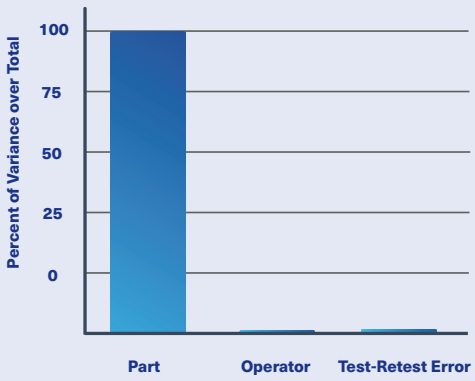
Product Variation:

Product variation should ideally be as high as possible. Differences between samples arise from sample variation rather than operator or gauge error. Variation above 80 percent is considered a “First-Class Gauge,” according to MiniTab.

Standard Deviation:

Standard deviation, influenced by MiniTab, calculated the gauge and operator's influence on measurements. Below are the drawing tolerances for reference.

Contribution of Variance Components



Gauge R&R Product Variation Definition

Detail	Description	P4k 4SP	P5k 4SP	P4k 16SP
1	Segment1 (diameter)	99.824%	99.910%	99.562%
2	Segment1 (length)	98.546%	98.504%	98.439%
3	Segment2 (length)	99.169%	99.709%	99.605%
4	Segment3 (diameter)	99.991%	99.960%	99.989%
5	Segment3 (length)	98.877%	99.692%	99.611%
6	Segment4 (length)	98.137%	99.588%	99.382%
7	Segment5 (diameter)	99.994%	99.992%	99.992%
8	Segment5 (length)	87.119%	92.304%	95.662%
9	Segment6 (length)	99.487%	99.912%	99.879%

Gauge + User Error STD

Detail	Description	P4k 4SP	P5k 4SP	P4k 16SP
1	Segment1 (diameter)	.000 009	.000 007	.000 012
2	Segment1 (length)	.000 480	.000 535	.000 498
3	Segment2 (length)	.000 465	.000 294	.000 356
4	Segment3 (diameter)	.000 002	.000 002	.000 004
5	Segment3 (length)	.005 318	.003 063	.003 909
6	Segment4 (length)	.006 719	.003 274	.003 970
7	Segment5 (diameter)	.000 002	.000 002	.000 002
8	Segment5 (length)	.020 490	.014 733	.013 864
9	Segment6 (length)	.029 973	.011 395	.011 744

Percentage of Tolerance Used by Gauge+User STD

Detail	Description	P4k 4SP	P5k 4SP	P4k 16SP
1	Segment1 (diameter)	1.1%	0.9%	1.6%
2	Segment1 (length)	4.8%	5.4%	5.0%
3	Segment2 (length)	0.5%	0.3%	0.4%
4	Segment3 (diameter)	0.3%	0.2%	0.4%
5	Segment3 (length)	2.7%	1.5%	2.0%
6	Segment4 (length)	3.4%	1.6%	2.0%
7	Segment5 (diameter)	0.2%	0.3%	0.3%
8	Segment5 (length)	10.2%	7.4%	6.9%
9	Segment6 (length)	15.0%	5.7%	5.9%

About MMT:

Medical Manufacturing Technologies (MMT), a **leading global provider of medical device and industrial manufacturing solutions**, is a single-resource solution for automated process-driven manufacturing—streamlining complex systems with an emphasis on precision and finely tuned efficiency. The company offers process development, applications and equipment, technical solutions, and after-market support.

Learn more at:

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