

Article

Analysis on Accuracy of Bias, Linearity and Stability of Measurement System in Ball screw Processes by Simulation

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Abstract: To consistently produce high quality products, a quality management system, such as the ISO9001, 2000 or TS 16949 must be practically implemented. One core instrument of the TS16949 MSA (Measurement System Analysis) is to rank the capability of a measurement system and ensure the quality characteristics of the product would likely be transformed through the whole manufacturing process. It is important to reduce the risk of Type I errors (acceptable goods are misjudged as defective parts) and Type II errors (defective parts are misjudged as good parts). An ideal measuring system would have the statistical characteristic of zero error, but such a system could hardly exist. Hence, to maintain better control of the variance that might occur in the manufacturing process, MSA is necessary for better quality control. Ball screws, which are a key component in precision machines, have significant attributes with respect to positioning and transmitting. Failures of lead accuracy and axial-gap of a ball screw can cause negative and expensive effects in machine positioning accuracy. Consequently, a functional measurement system can incur great savings by detecting Type I and Type II errors. If the measurement system fails with respect to specification of the product, it will likely misjudge Type I and Type II errors. Inspectors normally follow the MSA regulations for accuracy measurement, but the choice of measuring system does not merely depend on some simple indices. In this paper, we examine the stability of a measuring system by using a Monte Carlo simulation to establish bias, linearity variance of the normal distribution, and the probability density function. Further, we forecast the possible area distribution in the real case. After the simulation, the

measurement capability will be improved, which helps the user classify the measurement system and establish measurement regulations for better performance and monitoring of the precision of the ball screw.

Keywords: measurement system analysis; Monte Carlo simulation; bias; linearity; stability

1. Introduction

The ISO/TS 16949 core tool measurement system analysis (MSA) manual focuses on the evaluation of statistical analyses of the measurement system. Daniels and Burdick [1] noted that a measurement system must be properly applied to a process to ensure product quality is within acceptable standards. Product and measurement variation affect process variation, and measurement system analysis and sampling techniques are important keys to improving measurement capability [2]. To improve the accuracy required for various types of measuring instruments, companies have developed various quality measurement techniques. The ultimate goal of different measurement analysis determination methods is to find the total measurement variation, known as the uncertainty of measurement [3]. Data on processes are mostly obtained through measuring instruments, and the instruments themselves contain uncertainties. Through the use of MSA, the reliability of measurement results can be ensured, and this can contribute to the implementation of quality improvement plans [4]. Thus, an accurate and reliable measurement system analysis (MSA) not only ensures accurate process capability, but also aids scientific and industrial development [5]. Measurement system quality and product quality are clearly interconnected. In particular, effective control of the measurement system is crucial to ensure the quality.

Ball screws are indispensable key components for precision machinery in terms of accurate positioning and transmission. With the higher and more advanced demand for precision machine tools, the precision requirements for ball screws have also increased [6]. Factors affecting ball screw positioning accuracy include lead accuracy, axial clearance and axial rigidity of the feed screw system. Lead accuracy and axial clearance are two most importance factors for ball screw quality in practice. Therefore, in this study, external diameters or length of ball screw parts are measured to determine ball screw quality.

In addition to technology breakthroughs in design and technical aspects, effective management and control of the measurement system is also a fundamental requirement to ensure the reduction of errors. The objective for taking measurements is to ensure that products meet the specification requirements. If a measurement system itself has measurement errors, then the results will be misjudged [7]. In order for companies to maintain the production of high-quality products, they must have the right concepts for MSA. In addition, these concepts should be used in the precision measurement equipment, to ensure excellent product quality and the competitive position of the company [8]. The measurement purpose is to determine whether the products meet the specifications and safety requirements, while monitoring product quality properties to avoid type I errors (an acceptable product judged as defective) and type II errors (a defective product judged as acceptable). In particular, we focus on type II errors because the risk goes directly to the clients, causing serious customer complaints and costs due to

quality failure. Montgomery and Runger [9] stated that a measurement system should play an active key role in helping companies to improve their quality. It has become a top priority to effectively manage measurement systems. In our study, we hope to effectively control the accuracy variation for measurement systems, to ensure the precision of ball screws, and to optimize measuring systems.

2. Literature Review

2.1. ISO/TS 16949

Although automotive suppliers may obtain their certifications for QS 9000 or VDA 6.1 quality systems, these certifications are not recognized in all countries. Different countries and regions have their own set of quality management system standards for their automobile industry. To become a part of the global automotive supply chain, a large amount of money is required to obtain various quality management system certifications targeting different countries and regions [10]. Lupo [11] referred to these different quality management standards. With the assistance of the 176 Technical Committee in the International Standards Organization (ISO), the International Automotive Task Force (IATF) and the Japan Automobile Manufacturers Association (JAMA), ISO/TS 16949 was formed to provide the automotive industry suppliers a set of system quality management standards throughout the entire process including design, development, production and service. This has established a unified global standard for assessing quality management systems in the automotive industry. The current quality systems globally used in automotive industry comply with the ISO/TS 16949 Automotive Quality Management System. Therefore, by being compliant with the ISO/TS 16949 technical specification requirements, companies can avoid having multiple certification audits. ISO/TS 16949 certification represents the essence of automotive quality system standards in all countries. Through certification, products are considered to have high quality and value. By strengthening their quality management system, companies in the relevant industry also position themselves as different to others, thus developing the best way to enter the global market [12] and increasing a company's competitive advantage. In addition to the automotive industry, other industries are also keen to promote such implementation, which revolutionizes global changes in quality control systems [13]. ISO/TS 16949 contains the following five core tools, which make the requirements for quality management systems even more rigorous: (1) Advanced Product Quality Planning (APQP); (2) Production Parts Approval Process (PPAP); (3) Measurement System Analysis (MSA); (4) Failure Mode and Effects Analysis (FMEA); and (5) Statistical Process Control (SPC).

2.2. Measurement System Analysis (MSA)

Levinson [14] notes that measurement variability affects the performance of the process capability index and product quality, reducing the monitoring capability of statistical process control charts. If the measurement system is not sufficiently precise, the true value of the product is distorted. This is an impetus to improve the measurement system. In an ideal measurement system, the correct measurement results would be produced during each use [15]. In other words, the ideal measurement system should have the property of zero statistical error in terms of the products being tested [3]. However, such ideal measurement does not exist, and so we need to rely on measurement systems for

analysis and manage the variability in measurement systems to keep them within a reasonable range. Measurement System Analysis is a core tool in the ISO/TS 16949 quality management system. It uses mathematical statistics and graphical methods to perform experimental design and statistical analysis on the measurement system error in order to assess the variability of the measurement system. From this, we can identify variations in measuring instruments and field measurement staff [16]. However, ISO/TS 16949 placed instrument calibration and MSA specification under the same clause (Clause 7.6) and the main targets for MSA are instruments; hence, companies are likely to be confused and equate MSA and calibration, incorrectly, considering that MSA means calibration plus statistics [17]. Measurement system analysis, instrument correlation and calibration are all evaluation methods for measurement system, and regardless of which method is used, they are all used to evaluate the reliability of the measurement system and to ensure the process is stable [18].

2.3. Position Variability in Measurement Systems

Measurement system accuracy causes position variation in measurement systems. When the same person is using the same measuring tools to perform the same repeated measurement on the same object, accuracy is the bias between the gauge reading and the reference value of the object [15]. The measurement reading can be the average value of a single reading or multiple readings. The reference value is obtained by using the most accurate measuring device. Juran [19] defined measurement accuracy as the error in terms of difference between the observed value and the true value after performing long-term repeated tests multiple times on certain quality properties of a single product. The measurement error may be positive or negative. Reilly [20] defined accuracy as using the instrument to confirm samples and how close the measured value of the sample is to the true value. Grubbs [21] stated that position variation in measurement systems is actually the accuracy variation. Errors affecting the accuracy of the measurement system are bias, linearity and stability [22]. The MSA Guidebook [15] defines them as follows: (1) Bias: The difference between the average value obtained when the same person is using the same measuring instrument to measure the same property of the same part multiple times, and the true value or reference value obtained by measuring the same property of the same part using laboratory instrument. (2) Linearity: The bias within the operation scope of the measuring tools; in other words, the difference between the measured value and the standard value for different ranges. (3) Stability: At different times, the same person uses the same measuring tool to perform multiple measurements on the same quality properties of the same object, and then calculates the average measured value for each time period. Then, stability refers to the changes in measurement tools as time changes. If, for each time period, the average measured readings are similar, the measurement system has good stability.

Carman [23] first discussed the impact of linearity on the accuracy of the measurement system, and confirmed the quality of measuring techniques. In that study, the assumed linearity and additive property required by the internal measurement was relaxed, and the MANOVA (Multivariate Analysis of Variance) method was used to compare the measurement techniques. Snow *et al.* [24] calculated the acceptance or rejection probability caused by errors while the measurement system error is under uniform distribution and normal distribution. The research implies that the average value during the process, the accuracy in relation to the specification and the probability distribution of the measuring

system error can affect the risks of error acceptance or rejection. Senol [25] considered the risk involved for the manufacturers and the consumers and, while minimizing the number of samples required, applied experimental designs to find the optimal configuration for influencing factors for measurement system analysis, in order to improve measurement accuracy. Aguilar *et al.* [26] believed that the most important statistical property for 3D measurement devices was the fact that small bias and variation can produce measurement results that are close to traceable standard values. Other factors of a measurement system can generate additional sources of variation. Using optical 3D measurement devices for lots of the design change can improve the accuracy of the automobile body assembly quality. Yu *et al.* [27] proposed an assessment method for the capability of such 3D measurement devices using experiments involving partial fraction design, and standard gauge block with contact measurement methods to assess the efficacy of the measurement. In addition to inspecting gauge repeatability and reproducibility (GR&R), this study covered bias, linearity and stability for common measurement systems to ensure the precision and accuracy of the measurement system.

2.4. Monte Carlo Simulation Method

The Monte Carlo method is a computer simulation method. If, during the research process, random numbers are used to simulate tests or used directly as the test results, it is considered an application of the Monte Carlo method [28]. The Monte Carlo method originated in statistical sampling, and is also known as a statistical simulation method or random sampling technique [18]. Robert and Casella [29] stated that Monte Carlo simulation components must include the following: (1) The probability density function (pdf): a necessary function for physical (or mathematical) systems. (2) A random number generator: a source that can provide random numbers. (3) Sampling rules: take samples from designated pdf, with unit intervals are available to separate random numbers. (4) Calculation: output results must be accumulated to a total value, (5) Error estimation: estimated number of statistical errors or variations and the relationship with other numbers of function must be determined. (6) Change reduction technology: a method to reduce the number variation to reduce the computing time for Monte Carlo simulation. (7) Parallel and vertical integration: effectively implementing the application of Monte Carlo method in advanced computer system architecture.

Monte Carlo simulation is applied to various fields. For example, Estecahandy *et al.* [30] and Khazen and Dubi [31] employed Monte Carlo simulation to do reliability analysis of instrumented safety systems; Arnold and Yildiz [32] introduced Monte Carlo simulation to risk analysis of renewable energy; Gurgur and Jones [33] applied Monte Carlo simulation to predict capacity factor and power plan in the wind power generation industry; Gatti [34] used Monte Carlo simulation to design, structuring and financing private and public projects; and Amigun *et al.* [35] assess the risk of advanced process technologies for bioethanol production by Monte Carlo analysis. Because Monte Carlo simulation is a relevant option to obtain numerical results, in this study, Monte Carlo simulation method is chosen to analyze the accuracy of bias, linearity and stability of measurement system.

3. Research Methods

3.1. Research Steps

First, we confirm the stability of the key measurement system; in other words, after performing a statistical evaluation of the measurement system for a certain period, we use MSA accuracy analysis to assess the bias and linear relationship. Then, we apply the MSA bias and linear analysis method to a Monte Carlo simulation set up and configured in the computer software Crystal Ball (CB). This gives the estimated measurement system bias and linearity variation. Finally, the estimated results from the Monte Carlo simulation and the general MSA analysis results are compared.

Two different measuring tools are analyzed in separate case studies. Prior to MSA, accuracy analysis confirmed that the measuring system in this study does not have any reproducibility issues. Thus, during the course of the study, only one evaluator is required. Analysis measuring tools must be long-term and stable. That is, they should be under statistical process control, and variation should only occur by chance [36].

Therefore, in this study, we first ensure the stability of the measuring system before performing analysis on the bias and linearity. The research steps are as follows:

Step1: First, ensure the stability of the measuring system. For stability analysis, we use a graphical method. Choose a product that falls within the range and assign it as the standard sample. Take measurement of the standard sample 3 times a day, 5 times a week for 6 weeks, giving a total of 90 sets of data. Calculate the control limit of \bar{X} -bar and R control chart, as shown in Equations (1) and (2) below. Arrange the data in chronological order and plot them on the \bar{X} -bar and R control charts. Use the control chart to assess if it is out of the control range.

$$UCL = \bar{\bar{X}} + A_2\bar{R}, CL = \bar{\bar{X}}, LCL = \bar{\bar{X}} - A_2\bar{R} \text{ (control chart for average value)} \quad (1)$$

$$UCL = D_4\bar{R}, CL = \bar{R}, LCL = D_3\bar{R} \text{ (control chart for total distance)} \quad (2)$$

Step 2: Analyze whether the measurement system bias is acceptable. From the production line, take a part that falls within the center range and send it to a more advanced measurement system to confirm the reference value. Assign an evaluator to perform routine analysis and measure the sample using measuring tools 15 times. The measurement results are plotted on a histogram. Histogram analysis is performed to determine if there appears to be any special factor or abnormality.

Step 3: Calculate the mean, standard deviation for reproducibility and T statistic bias for measurement readings, as shown in Equations (3)–(5) below. If 0 falls within the bias confidence interval, then a bias at the significance level of α is considered acceptable, as per Equation (6) below.

$$\bar{\bar{X}} = \frac{\sum_{i=1}^n x_i}{n} \quad (3)$$

$$\sigma_{repeatability} = \frac{\max(x_i) - \min(x_i)}{d_2^*} \quad (4)$$

$$t = \frac{bias}{\sigma_b} \quad (5)$$

$$Bias - \left[\frac{d_2\sigma_b}{d_2^*} \left(t_{v,1-\frac{\alpha}{2}} \right) \right] \leq zero \leq Bias + \left[\frac{d_2\sigma_b}{d_2^*} \left(t_{v,1-\frac{\alpha}{2}} \right) \right] \quad (6)$$

Step 4: Analyze the linearity of the measuring system. Select 5 parts, $g = 5$. Due to process variations, the measured values for the parts cover the operating range of the measuring tools. More advanced measuring tools are used to determine the reference values for each part, and then an evaluator is assigned to perform repeated measurements for each part 12 times. To maintain statistical independence between measurement results, random selection is used during the process. At the end of the measurement, measurement bias and average bias is calculated for each part. A regression line is calculated, where a is the slope and b is the intercept, as shown in Equation (7) below. Calculate the α confidence interval, as shown in Equation (8) below.

$$\bar{y}_i = ax_i + b, a = \frac{\sum xy - \left(\frac{1}{gm} \sum x \sum y\right)}{\sum x^2 - \frac{1}{gm} (\sum x)^2} \text{ et al } b = \bar{y} - a\bar{x} \quad (7)$$

$$b + ax_0 \pm \left[t_{gm-2, 1-\frac{\alpha}{2}} \left(\frac{1}{gm} + \frac{(x_0 - \bar{x})^2}{\sum (x_i - \bar{x})^2} \right)^{\frac{1}{2}} s \right], s = \frac{\sqrt{\sum y_i^2 - b \sum y_i - a \sum x_i y_i}}{gm - 2} \quad (8)$$

Step 5: Draw a straight line for bias 0, and review the diagram to observe whether there are special factors. If the entire straight line for bias 0 is located within the confidence interval, the linearity for the measuring system is acceptable.

Step 6: If the diagram analysis indicates that the linearity is acceptable, then assume $H_0: a = 0$ and slope = 0 are true. If the below Equation (9) is true, then it cannot be denied. If $H_0: a = 0$ and slope = 0 are assumed to be true, then the measurement system should have the same bias for all the reference values. In other words, suppose $H_0: b = 0$ and bias are 0, then the linearity is acceptable. If Equation (10) is true, then the above assumptions are not denied.

$$|t| = \frac{|a|}{\frac{s}{\sqrt{\sum (x_j - \bar{x})^2}}} \leq t_{gm-2, 1-\frac{\alpha}{2}} \quad (9)$$

$$|t| = \frac{|b|}{\sqrt{\frac{1}{gm} + \frac{\bar{x}^2}{\sum (x_i - \bar{x})^2}}} s \leq t_{gm-2, 1-\frac{\alpha}{2}} \quad (10)$$

3.2. Set up Monte Carlo Simulation

Using the accuracy analysis method developed in the MSA manual as a reference, we calculate bias and linearity of the key measurement system. Calculations are performed using the Monte Carlo simulation software (Crystal Ball). We generate random variables for the parameters a total of 10,000 times. This generation is done through the use of the Monte Carlo analysis method in Crystal Ball, and the congruential random number method described earlier. Based on the simulated measurement values, we aim to obtain bias and linearity variation which are more useful.

Yeh and Sun [37] pointed out that the measurement uncertainty developed by the MSA is a range given by the values of the measurement results. Within a predetermined level of confidence, it describes the range that is expected to contain true measurement results. Measurement uncertainty is usually bidirectional. Uncertainty is a quantitative expression of the reliability of the measurement. As shown in Equation (11), U is an expanded uncertainty of the measured object and the measurement results. The combined standard error (U_c) during the measurement process multiplied by the normal distribution coefficient (K) represents the expected range of reliability. ISO/IEC Guide 98-3 [38] confirms that the distribution coefficient $K = 2$, where K represents 95% of the normal distribution of uncertainty. As per Equation (12) below, this means that the observed measurements will fall within the range of $\pm 2\sigma$ from the average value, which is the 95% confidence interval. A collaborative assessment experiment in ISO 5725-1: 1994 [39] mentioned that, when multiple experiments are involved in a precision test, the probability level will be approximately 95%.

$$\text{True measurement} = \text{observed measurement (result)} \pm U \quad (11)$$

$$U = KU_c \quad (12)$$

Using the accuracy analysis developed by MSA, and together with Monte Carlo simulation, accuracy analysis conditions are determined using one evaluator using the same measuring tools. For bias analysis, we select a sample and measure it 15 times to get 15 measured values. For linear analysis, 5 samples are selected and measured 12 times to obtain a total of 60 measured values. We first define the Monte Carlo simulation with a normal distribution $\pm 2\sigma$. The ranges of values configured for the Monte Carlo simulation are shown as samples in Table 1, and the results are shown in Equation (14) below and Figure 1. We then set the calculated value to be the initial value of the original measured value.

$$f(x) = \frac{1}{\sqrt{2\pi}\sigma} e^{-(x-\mu)^2/2\sigma^2} \quad (13)$$

$$f(x) = \frac{1}{\sqrt{2\pi} \times 0.0013} e^{\frac{-(x-11.1999)^2}{2 \times 0.0013^2}} \text{ for } 11.1973 < X < 11.2005 \quad (14)$$

Table 1. Monte Carlo simulation sample configuration.

Monte Carlo Simulation Specification				
Sample	Mean (μ)	Standard Deviation (σ)	X	
			Max ($\mu + 2\sigma$)	Min ($\mu - 2\sigma$)
No.1	11.1999 mm	0.0013 mm	11.2025 mm	11.1973 mm

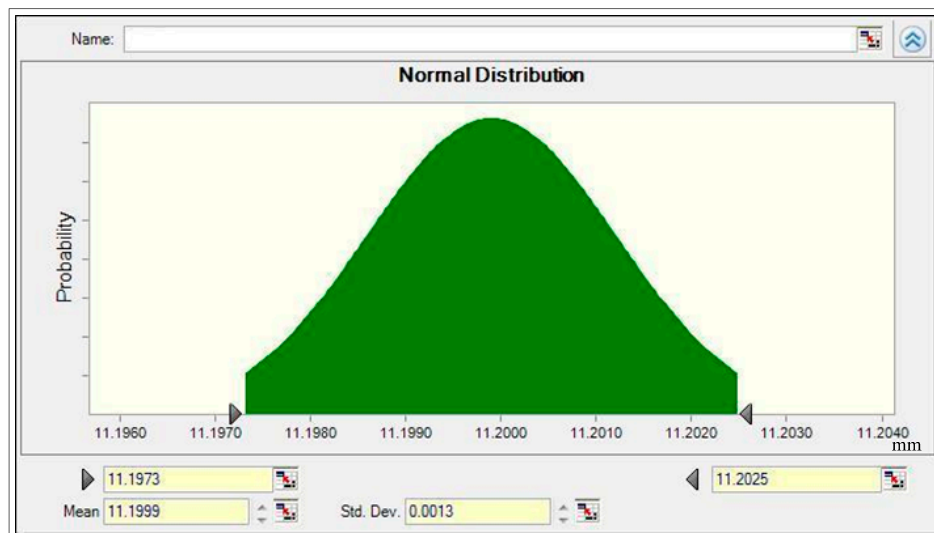


Figure 1. Sample No. 1 probability distribution for measured values.

4. Case Study

4.1. Case Information

In our study, we used a Taiwanese manufacturer of precision linearity transmission components as our case study. We used experimental methods and procedures to perform accuracy analysis on measurement systems using key measuring tools. First, we confirmed the measurement system stability, and then we performed analysis on the bias and linearity. Finally, we used a Monte Carlo simulation to predict bias and linearity variation characteristics. Based on the simulation results, we propose recommendations as references for the industry in the aspects of developing measurement system accuracy specifications and follow-up studies. In order to obtain the real measurement system for the measuring system, the design we used in this study for data collection uses measurements during the actual process, as described below:

- (1) We used actual production equipment.
- (2) The evaluators were Quality Control (QC) staff who frequently use the device.
- (3) Measurements were made with measuring tools that are regularly used.
- (4) Data were collected according to the plan, and case studies were performed twice.
- (5) In terms of stability, we had one measuring staff member, one measurement system, and one sample part; measurements were performed three times a day, five times a week for six weeks.
- (6) In terms of bias, we had one measuring staff member, one measurement system, and one sample part; measurements were performed 15 times.
- (7) In terms of linearity, we had one measuring staff member, one measurement system, and five sample parts; measurements were performed 12 times on each part.

4.2. Case 1

Measuring instruments with the code PG-02 are dial gauges. PG-02 and OG-04 are two of the most used instruments to measure external diameters of ball screw parts. In Case 1, PG-02 was used and

OG-04 was used in Case 2. The measured value obtained accurate to 0.001 mm. The evaluator was a QC staff member who frequently uses this measuring device. We first performed stability analysis. The standard sample was a ball screw drive coded 02A. We performed measurements three times a day, five days a week for a total of six weeks. The measured data are shown in Tables 2 and 3. We used Equations (1) and (2) to calculate the control limits. The actual measurement data and the control limits were chronologically plotted onto the \bar{X} -bar and R control charts, as shown in Figures 2 and 3. We analyzed and reviewed whether the control chart had any special factors or abnormal conditions. Since no special trend was observed and the control limits were not crossed, we determined that the stability was acceptable.

We then used the Monte Carlo method to simulate bias variation for the measuring tool coded PG-02. The simulated upper limit for the 95% confidence interval of the bias showed a normal distribution, with a simulated average of 0.0012. For the simulation data, the standard deviation for the degree of dispersion was 0.0006. The original value of 0.0014 falls within the range of $\pm\sigma$. This means that for the degree of dispersion between the sample average and the regression line, the standard error of the mean (SEM) is 0.0000, indicating that the simulated data are very close to the regression line, and the reliability of the simulated data is high.

Table 2. Measurement data for PG-02 stability analysis.

Day	X1	X2	X3	Day	X1	X2	X3
1	14.000	14.003	13.999	16	13.999	13.996	14.000
2	14.000	14.005	14.001	17	14.003	14.000	14.001
3	14.005	14.000	13.998	18	14.000	14.000	14.000
4	14.000	14.003	13.996	19	14.000	14.005	14.000
5	14.000	14.003	14.000	20	14.002	14.000	14.001
6	14.000	14.002	14.001	21	14.003	14.000	14.000
7	13.999	14.002	13.997	22	14.002	13.996	14.000
8	13.996	13.997	14.002	23	14.000	14.003	14.000
9	14.000	14.003	14.000	24	14.005	14.000	14.003
10	14.001	14.000	14.002	25	13.998	14.000	14.000
11	14.000	14.004	14.000	26	14.000	13.997	14.000
12	14.000	13.997	14.000	27	14.000	14.003	14.001
13	14.000	13.999	14.003	28	14.000	13.997	14.000
14	14.000	14.002	14.000	29	14.000	14.001	13.998
15	14.000	14.000	14.005	30	14.003	13.999	14.000

unit: mm.

Table 3. PG-02 measured data for PG-02 bias analysis.

Sequence	1st	2nd	3rd	4th	5th
Measured Results	22.004 mm	22.002 mm	22.002 mm	21.996 mm	21.999 mm
Sequence	6th	7th	8th	9th	10th
Measured Results	21.999 mm	22.005 mm	22.000 mm	21.998 mm	22.000 mm
Sequence	11th	12th	13th	14th	15th
Measured Results	22.002 mm	22.004 mm	22.002 mm	21.998 mm	22.004 mm

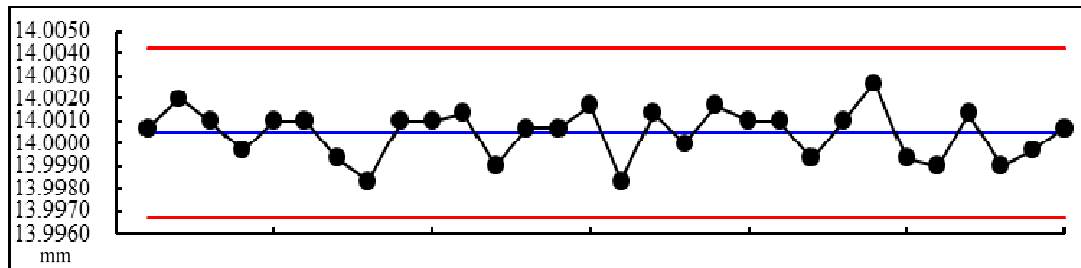


Figure 2. *X*-bar control chart for PG-02 stability analysis.

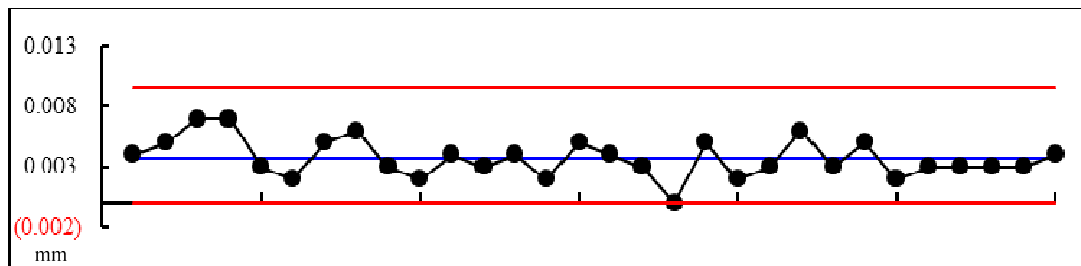


Figure 3. *R* chart for PG-02 stability analysis.

According to bias specifications in the MSA guidelines, the minimum requirement is that the upper limit for the confidence interval should be ≥ 0 . Based on the Monte Carlo simulation results, there are 9707 entries of simulated data that are ≥ 0 . The estimated acceptance probability is 97.07%, as shown in Figure 4. The simulated lower limit for the 95% confidence interval of the bias showed a normal distribution. The simulated average was -0.0013 . For the simulation data, the standard deviation for the degree of dispersion was 0.0006. The original value of -0.0014 falls within the range of $\pm\sigma$. This means that for the degree of dispersion between the sample average and the regression line, the SEM is 0.0000, indicating that the simulated data are very close to the regression line, and the reliability of the simulated data is high. According to bias specifications in the MSA guidelines, the lower upper limit for the confidence interval should be ≤ 0 . Based on the Monte Carlo simulation results, there were 9728 entries of simulated data that are ≤ 0 . The estimated acceptance probability was 97.28% as shown in Figure 5. Results of analysis on the Monte Carlo simulation for the 95% confidence interval for the bias were in accordance to the evaluation standards in the MSA for bias, and 0 fell within the 95% confidence interval for the bias. At the end of the simulation, there were 9434 entries (94.34%) of data that satisfied the bias requirement in the MSA guidelines. After simulation analysis and evaluation, the bias did not appear to have significant abnormalities. For a good measurement system, the bias obtained should be the same regardless of the size of the quantity [40]. To be extra cautious, and to further evaluate the PG-02 linearity variation in the measurement system, we simulated the amount of changes for the bias within the expected operating scope, in order to use as a reference to determine the ability of the measurement system.

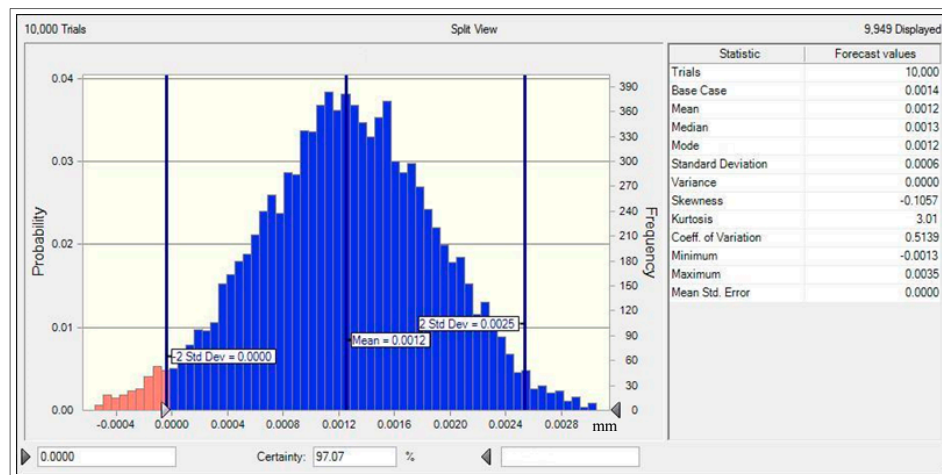


Figure 4. Distribution of the upper limit of the 95% confidence interval for simulated PG-02 bias analysis.

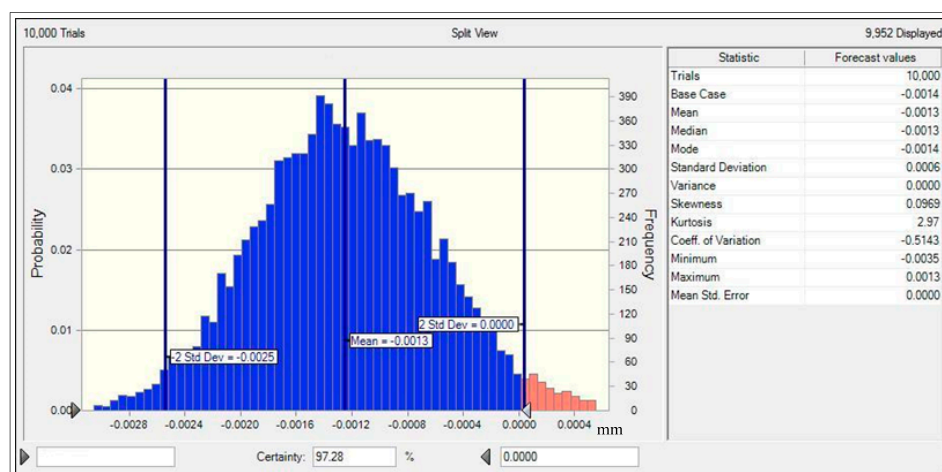
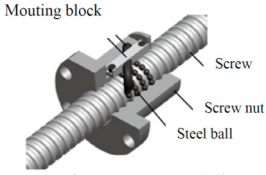


Figure 5. Distribution of the lower limit of the 95% confidence interval for simulated PG-02 bias analysis.

Finally, we performed linearity analysis. The measured values covered the operating range for the measuring tool dial gauge coded PG-02. We selected five parts and performed measurements on the same quality property 12 times for each part. Specifications and reference values for the parts are shown in Table 4. We used Equation (7) to calculate the slope and the intercept of the line to obtain the best-fit line. The confidence interval was calculated as per Equation (8). The calculated results are shown in Table 5. It was observed that for bias to be 0, the line must be located within the confidence interval. The linearity for the PG-02 dial gauge was acceptable. Since the linearity was acceptable as per the graphical method, and we assumed $H_0: a = 0$, we then were able to calculate the results using Equation (9) to be $|t| = 0.3508 \leq 2.0017$, and so that we cannot reject the assumption. If the assumptions that $H_0: a = 0$ and slope = 0 are true, then the measurement system should have the same bias for all the reference values. For an acceptable linearity, the bias must be 0. Assume that $H_0: b = 0$ and the results from Equation (10) show that $|t| = 0.2391 \leq 2.0017$, and therefore we cannot reject the assumption. Based on the standards for accuracy analysis in the MSA measurement system followed by the industry, the linearity for the PG-02 measurement system is acceptable.

Table 4. Specification for measured dimensions for linearity analysis.

Ball Screw Structure and Measurement	Part No. and Part Name	Drawing Dimension Specifications	3D Measurement Reference Value
	01A Drive screw	5.000 mm \pm 0.008 mm	5.002 mm
	02A Drive screw	14.000 mm \pm 0.01 mm	14.003 mm
	X5C Screw nut	22.000 mm \pm 0.012 mm	22.004 mm
	D4E Screw mounting block	27.000 mm \pm 0.012 mm	26.996 mm
	B5A Drive screw	41.000 mm \pm 0.012 mm	40.997 mm

Measurement: external diameters of screw, or external diameters of screw nut, and length of mounting block

Table 5. Data for PG-02 linear analysis.

x_i	Reference Value	Upper Limit for Confidence Interval	Lower Limit for Confidence Interval	Regression Line
1	5.002 mm	0.0014 mm	−0.0011 mm	0.0002 mm
2	14.003 mm	0.0009 mm	−0.0008 mm	0.0001 mm
3	22.004 mm	0.0007 mm	−0.0008 mm	−0.0002 mm
4	26.996 mm	0.0007 mm	−0.0009 mm	−0.0001 mm
5	40.997 mm	0.0011 mm	−0.0016 mm	−0.0003 mm

4.3. Case 2

Measuring instruments with the code OG-04 are dial gauges. The measured data were accurate to 0.001 mm. The evaluator was a QC staff member who frequently uses this measuring device. We first performed stability analysis. The standard sample as a ball screw drive coded as 02A. We performed measurements three times a day, five days a week for a total of six weeks. The measured data are shown in Table 6. We used Equations (1) and (2) to calculate the control limits. The actual measurement data and the control limits were chronologically plotted onto the \bar{X} -bar and R control charts as shown in Figures 6 and 7. We analyzed and reviewed whether the control chart had any special factors or abnormal conditions. Since no special trend was observed and the control limits were not crossed, we determined that the stability is acceptable.

Table 6. Measurement data for OG-04 stability analysis.

Day	$X1$	$X2$	$X3$	Day	$X1$	$X2$	$X3$
1	13.997	14.006	13.999	16	13.999	13.996	14.005
2	14.001	14.002	14.007	17	14.003	14.005	14.001
3	14.005	14.004	13.996	18	14.000	14.003	14.000
4	14.004	14.006	13.997	19	14.000	14.005	13.997
5	14.002	14.003	14.005	20	14.005	14.002	14.001
6	14.005	14.002	13.998	21	14.003	13.999	14.004
7	14.001	14.004	14.002	22	14.002	13.996	14.005
8	14.006	13.997	14.005	23	14.000	14.003	13.998
9	14.005	14.007	13.999	24	14.005	14.005	14.003
10	14.006	14.005	14.002	25	13.998	14.000	14.004

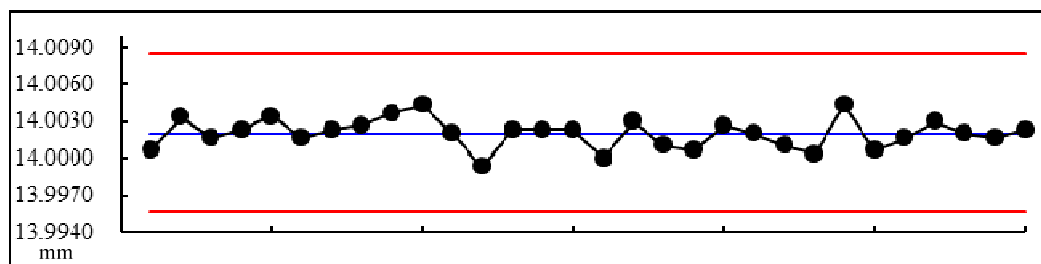
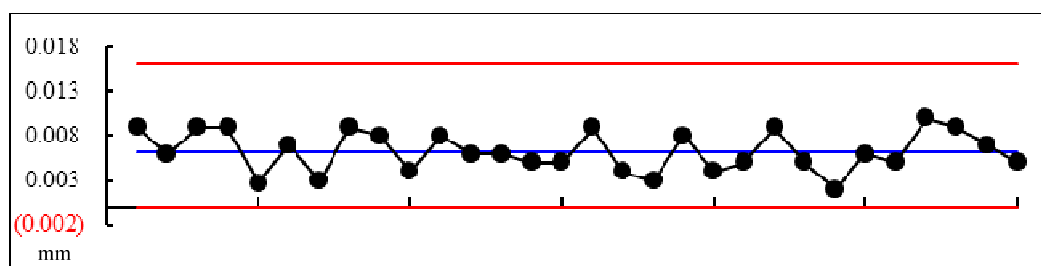
Table 6. *Cont.*

Day	X1	X2	X3	Day	X1	X2	X3
11	13.997	14.004	14.005	26	14.000	14.000	14.005
12	14.003	13.997	13.998	27	14.005	13.997	14.007
13	14.005	13.999	14.003	28	14.003	13.997	14.006
14	14.000	14.005	14.002	29	14.002	14.005	13.998
15	14.000	14.002	14.005	30	14.005	14.000	14.002

unit: mm.

We then performed bias analysis. The standard samples were ball screw nuts coded X5C. Repeated measurements were performed in terms of the length of the sample for a total of 15 times (Table 7). The measured data are shown in Figure 5. The standard reference value for this sample X_T was 22.001 mm. The measured data were plotted on a histogram as shown in Figure 8. Based on the graphical method, there were no special factors or abnormalities. Equations (3) and (4) were used to calculate the bias. It was calculated that the confidence interval for the 95% bias is $[-0.0036, 0.0002]$. Therefore, the bias is above the α level and is acceptable.

$$Bias - \left[\frac{d_2 \sigma_b}{d_2^*} \left(t_{v, 1 - \frac{\alpha}{2}} \right) \right] \leq zero \leq Bias + \left[\frac{d_2 \sigma_b}{d_2^*} \left(t_{v, 1 - \frac{\alpha}{2}} \right) \right] = -0.0036 \leq zero \leq 0.0002$$

**Figure 6.** *X*-bar control chart for OG-04 stability analysis.**Figure 7.** *R* chart for OG-04 stability analysis.**Table 7.** OG-04 measured data table for PG-02 bias analysis.

Sequence	1st	2nd	3rd	4th	5th
Measured Results	21.998 mm	21.998 mm	22.000 mm	21.997 mm	22.006 mm
Sequence	6th	7th	8th	9th	10th
Measured Results	21.999 mm	21.995 mm	22.003 mm	21.999 mm	21.993 mm
Sequence	11th	12th	13th	14th	15th
Measured Results	22.001 mm	21.996 mm	22.002 mm	21.999 mm	22.004 mm

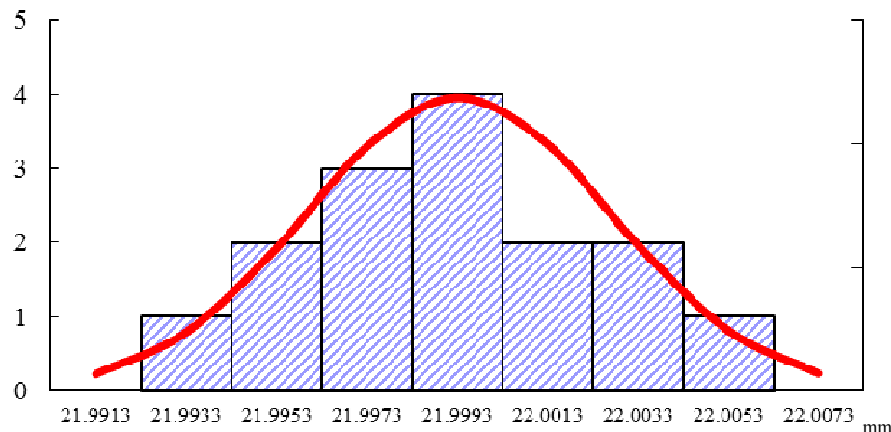


Figure 8. OG-04 bias histogram analysis.

We used Monte Carlo to simulate bias variation for the measuring tool coded OG-04. The simulated upper limit for the 95% confidence interval of the bias showed a normal distribution, with a simulated average of -0.0001 . For the simulation data, the standard deviation for the degree of dispersion was 0.0008 . The original value of 0.0002 falls within the range of $\pm\sigma$. This means that for the degree of dispersion between the sample average and the regression line, the SEM is 0.0000 , indicating that the simulated data are very close to the regression line, and the reliability of the simulated data is high. According to the bias specifications in the MSA guidelines, the minimum requirement is that the upper limit for confidence interval should be ≥ 0 . Based on the Monte Carlo simulation results, there were 4727 entries of simulated data that were ≥ 0 . The estimated acceptance probability was 47.27% as shown in Figure 9. The simulated lower limit for the 95% confidence interval of the bias showed a normal distribution. The simulated average was -0.0033 . For the simulation data, the standard deviation for the degree of dispersion was 0.0008 . The original value of -0.0036 falls within the range of $\pm\sigma$. This means that for the degree of dispersion between the sample average and the regression line, the SEM is 0.0000 , indicating that the simulated data are very close to the regression line, and the reliability of the simulated data is high.

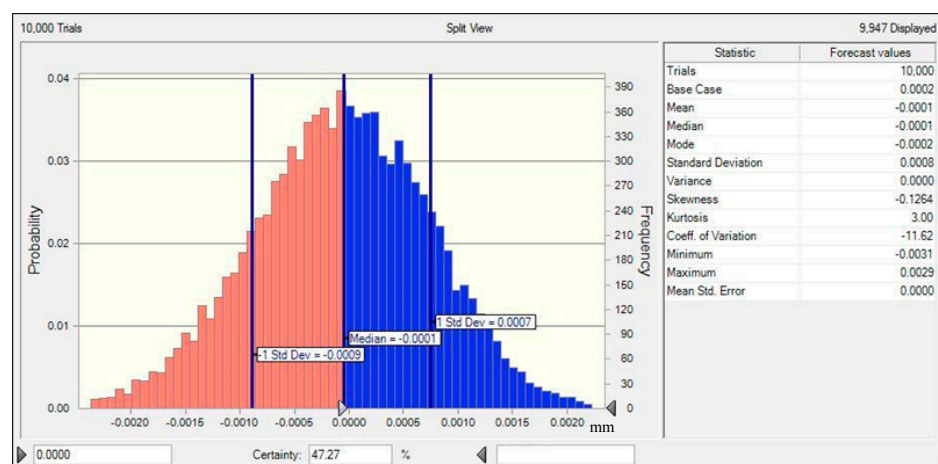


Figure 9. Distribution of the upper limit of the 95% confidence interval for simulated OG-04 bias analysis.

According to the bias specifications in the MSA guidelines, the lower limit for the confidence interval should be ≤ 0 . Based on the Monte Carlo simulation results, there were 10,000 entries of simulated data that were ≤ 0 . The estimated acceptance probability was 100% as shown in Figure 10. Result Analysis on the Monte Carlo simulation for 95% confidence interval for the bias was in accordance with the evaluation standards in the MSA for bias, such that 0 must fall within the 95% confidence interval for the bias. At the end of the simulation, there are 4727 entries (47.27%) of data that satisfy the bias requirement in the MSA guidelines. After simulation analysis and evaluation on the measurement system OG-04, the abnormal rate for the upper limit of the 95% confidence interval for the bias was high, since the observed value was lower than the reference value. It was recommended that before making a further determination to see if a change in the procedure is needed (for example, use the bias to adjust every single reading method), an assessment of the simulated linearity analysis was required.

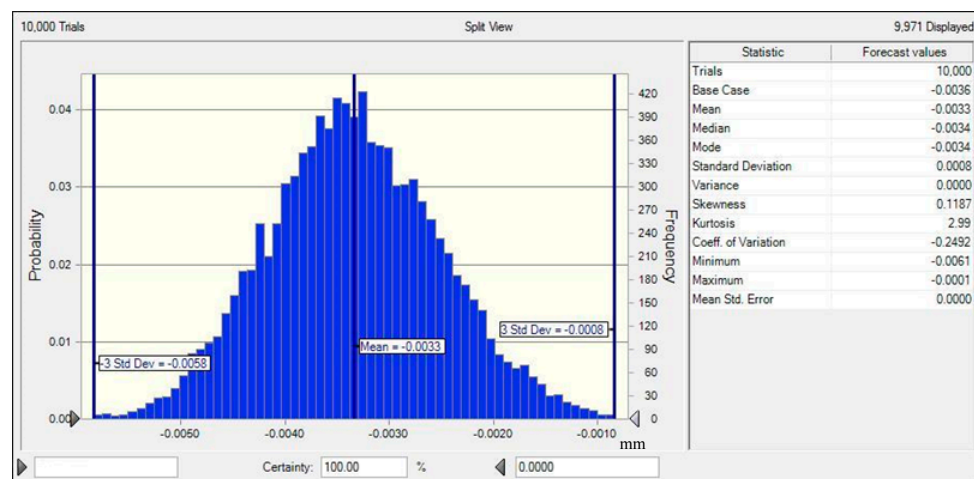
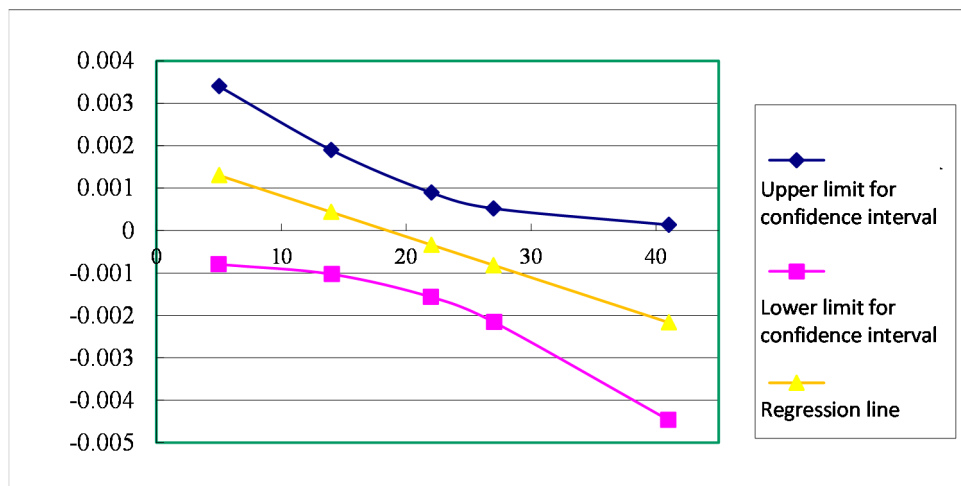


Figure 10. Distribution of the lower limit of the 95% confidence interval for simulated OG-04 bias analysis.

Finally, we performed linearity analysis. The measured values covered the operating range for the measuring tool dial gauge coded OG-04. We selected five parts and performed measurements on the same quality property 12 times for each part. Specifications and reference values for the parts are shown in Table 4. We used Equation (7) to calculate the slope and the intercept of the line to obtain the best-fit line. The confidence interval was calculated as per Equation (8). The calculated results are shown in Table 8. It is observed that for bias to be 0, the line must be located within the confidence interval. The linearity for the OG-04 dial gauge is acceptable as per Figure 11. If the graphical linearity is acceptable, and we assume $H_0: a = 0$ is true, then using Equation (9) we can calculate the results to be $|t| = 1.9045 \leq 2.0017$, and so that we cannot reject the assumption. If the assumption that $H_0: a = 0$, slope = 0 is true, then the measurement system should have the same bias for all the reference values. For an acceptable linearity, the bias must be 0. Assume that $H_0: b = 0$, results from Equation (10) show that $|t| = 1.4126 \leq 2.0017$, and therefore we cannot reject the assumption. Based on the standards for accuracy analysis in the MSA measurement system followed by the industry, the linearity for the OG-04 measurement system is acceptable.

Table 8. Data for OG-04 linear analysis.

x_i	Reference Value	Upper Limit for Confidence Interval	Lower Limit for Confidence Interval	Regression Line
1	5.002 mm	0.0034 mm	−0.0008 mm	0.0013 mm
2	14.003 mm	0.0019 mm	−0.0010 mm	0.0004 mm
3	22.004 mm	0.0009 mm	−0.0016 mm	−0.0003 mm
4	26.996 mm	0.0005 mm	−0.0022 mm	−0.0008 mm
5	40.997 mm	0.0001 mm	−0.0045 mm	−0.0022 mm

**Figure 11.** OG-04 linearity analysis.

Through the Monte Carlo simulation, linearity analysis was performed on the resultant T_a value, and it appeared to be a beta distribution. The standard simulated value was 1.9045, the simulated average was 2.1722, and the simulated standard deviation for the degree of information dispersion was 0.9700. The original value 1.9045 falls within the range of $\pm\sigma$. This means that for the degree of dispersion between the sample average and the regression line, the SEM is 0.0097, indicating that the simulated data are reliable. According to specifications in the MSA guidelines, if T_a is less than 2.0017, then the assumptions $H_0: a = 0$ and slope = 0 may hold. Based on the Monte Carlo simulation results, there are 9163 entries of simulated T_a that are less than 2.0017. The estimated acceptance probability was 44.05%, as shown in Figure 12. The Monte Carlo simulation showed that the resultant T_b appeared to be a beta distribution. The standard simulated value was 1.4126, the simulated average was 1.6727, and the simulated standard deviation for the degree of information dispersion was 0.8602. The original value 1.4126 falls within the range of $\pm\sigma$. For the degree of dispersion between the sample average and the regression line, the standard error (SEM) is 0.0086. According to specifications in the MSA guidelines, if T_b is less than 2.0017, then the assumptions that $H_0: b = 0$ and bias = 0 may hold. Based on the Monte Carlo simulation results, there are 6580 entries of simulated T_b that are less than 2.0017. The estimated acceptance probability was 65.08%, as shown in Figure 13. Finally, we have the estimated linearity results using the Monte Carlo simulation. According to linearity specifications in the MSA guidelines, if T_a and T_b are less than 2.0017, then the assumptions $H_0: a = 0$ and $H_0: b = 0$ may hold. Thus, these assumptions are true. The above linearities are acceptable. At the end of the simulation analysis, there were 4235 entries (42.35%) of data that satisfied the linearity requirement in

the MSA guidelines. After simulation, it was determined that the linearity variation for the measurement system 0G-04 may exceed the acceptable range. The measurement system needs to be adjusted so that it can have 0 bias. If the bias in the measurement range cannot be adjusted to zero, then the measurement system can only be used when it is stable, and also only for process and product control. The measurement system cannot be used in analysis.

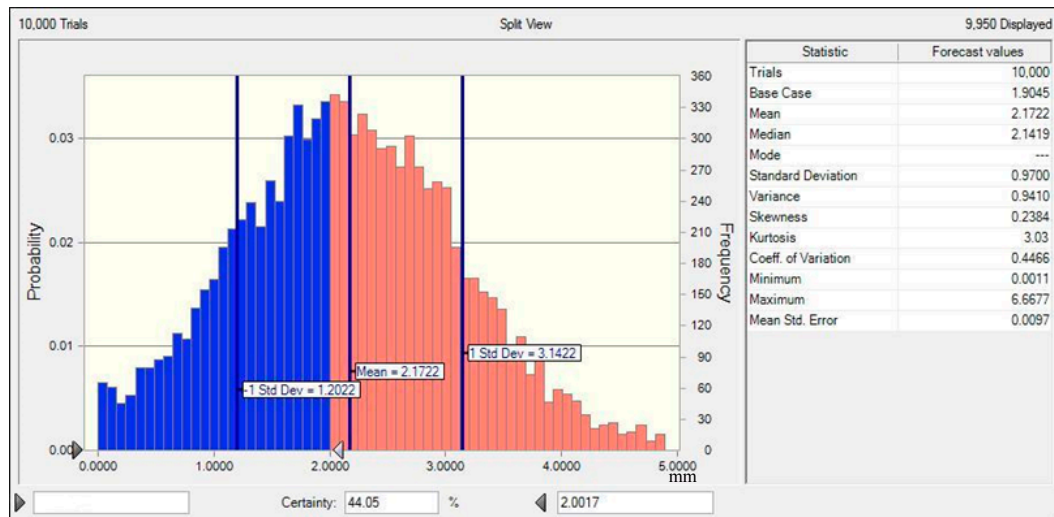


Figure 12. T_a distribution for OG-04 linearity analysis.

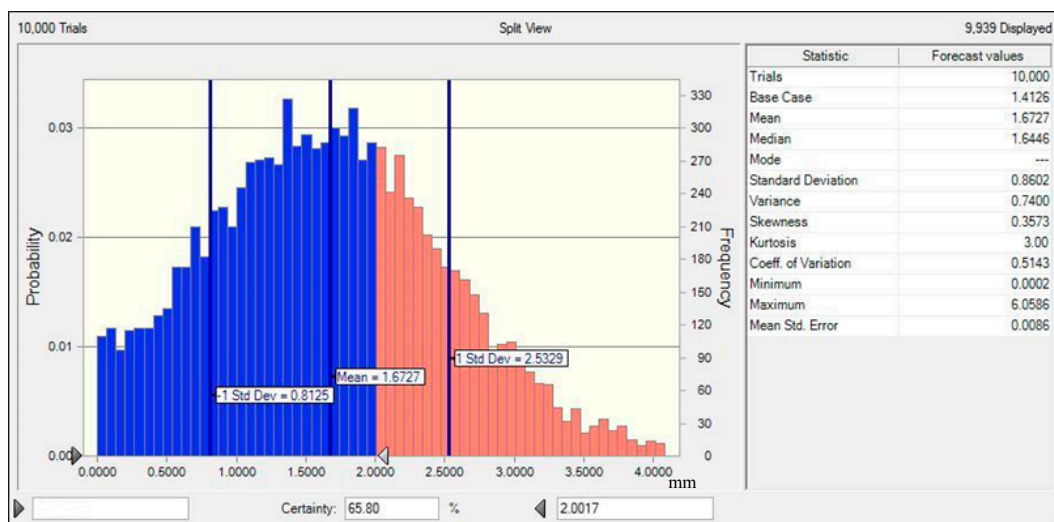


Figure 13. T_b distribution for OG-04 linearity analysis.

4.4. Comparison of Results and Discussion

From the case studies, it was observed that all the measurement systems had stabilities. That is, for the same measured object, the measurement system would have the same measurement results regardless whether the measurement was performed right now or in the future [40]. For measuring instruments coded PG-02, after performing MSA bias analysis, the resultant 95% confidence interval for bias was $[-0.0014, 0.0014]$, and for measuring instruments coded OG-04, after performing MSA bias analysis, the resultant 95% confidence interval for bias was $[-0.0036, 0.0002]$. For both, 0 fell

within the 95% confidence interval. Using the conventional MSA bias analysis, no abnormalities were found for the bias. To perform a clearer investigation on the bias characteristic for the measurement systems, we used Monte Carlo simulations in this study to simulate actual case data to perform verification. For Case 1, the acceptance for bias was 94.34%. For Case 2, the acceptance for bias was only 47.27%. Linear analysis should be carried out immediately in order to obtain more accurate information. In the scope of this work, when a measuring tool is used to perform measurement on properties of different sizes, the bias can also be different. The linearity of a measuring system is also a statistical property that represents the bias variation within the scope of the work [41]. The measurement systems should have accurate measurement results within the measurable range. In other words, they should have linearity [40].

After linear analysis, the graphical chart analysis on measuring instruments coded PG-02 showed that the 0 bias line falls within its 95% confidence intervals for bias points, and the T_a (0.5191), T_b (0.3750) values were less than 2.0017. Linearity abnormalities for the measurement system could not be excluded. After linear analysis, the graphical chart analysis on the measuring instruments coded OG-04 shows that the 0 bias line falls within its 95% CI intervals for bias points, and the T_a (1.8691) and T_b (1.3885) values are less than 2.0017. Linearity abnormalities for the measurement system could not be excluded, according to the standard for accuracy analysis for MSA measurement systems. However, from the information, it was observed that linearity is determined by the slope. A lower slope means a better linearity. For Case 1, the slope was -0.0001 . For Case 2, the slope was -0.0009 . It was determined that the linearity in Case 2 was relatively poor, and careful assessment is required for accuracy variation. Using a Monte Carlo simulation to simulate linear analysis, the linearity acceptable level for Case 1 was 90.26%, and for Case 2, only 42.35% of the simulated data were acceptable.

After performing MSA measurement system linearity analysis, both study cases show that the abnormalities could not be determined. However, the company in the case study is a manufacturer of precision linear transmission components, and is especially in need of accurate determination of variation in the measurement systems to ensure proper measurement systems can convey the characteristics of the measured items. This would effectively improve product quality and competitiveness of the company. After obtaining reports and recommendations from the Monte Carlo simulation data analysis, the case company immediately checked the measurement system coded OG-04, which had poor simulation results. After the assessment by the quality control department, it was found that the probe in the measuring instrument OG-04 had wear and tear, and that it also had improper calibration in terms of the high and low measurement range. This may result in poor measurement accuracy, and decrease the capability of producing a good measurement. After verification with the actual case, it was recommended that the company use the Monte Carlo simulation method when performing accuracy analysis of the measurement system in future. The estimated passing rate can be used as a reference index to classify the capabilities of measuring tools, and also configure related specifications. For example, measuring tools that are below the 60% passing rate should be evaluated and improved immediately to ensure measurement accuracy.

5. Conclusions

Although the MSA and verification tests are different, we can reference the analytical methods in the MSA in terms of the bias and linearity to improve the calibration system. Statistical examination can replace conventional verification standards, which use the maximum permissible deviation between the readings and the standard values [17]. While assessing the uncertainty of the instrument calibration system, if we take the linearity within the measurement (calibration) range into account, we can perform a more comprehensive assessment. Using uncertainty to express the reasonable interval range, decentralized model, and acceptable reliabilities of the “true value”, the measurement results can go through certain modules that offer statistics and analysis, and become credible, safe, economical and feasible. During the measurement, there are many random factors that may cause measured output values in the process to be random variables. While the process has many random factors, if the operation is stable during the measurement process, then the impact of each factor is insignificant. The results of their combined effects often cause the measured values to exhibit a normal distribution. Therefore, in measurement system analysis, normal distribution plays an important role [41].

Thus, in this study, we used Monte Carlo simulation combined with statistical concepts and measurement uncertainty to establish a normal distribution and probability density functions. Based on the MSA accuracy analysis, we simulated an estimation model to assess the possible ranges for bias and linearity variation in the measurement systems. Using the company in the case study as an example, we verified our system, and found that this model can be effectively used by the company. It can correctly assess the capabilities of the measurement systems. In addition, the analysis results can also be effectively used to improve and maintain the measuring tools, and also to grade the measuring tools. Measurement systems with poor simulated accuracy should have restrictions for usage, and should be calibrated and maintained so that they can recover and return to the existing measurement standards. This avoids measurement error due to the measurement system, which can affect product quality and result in reputation impairment. The conclusions for our study are as follows:

(1) Using a Monte Carlo simulation combined with MSA [15] bias and linear analysis, we can provide a clearer determination on the capabilities of measurement systems. Compared with conventional MSA methods for accuracy bias and criteria for linearity, our system is more rigorous.

(2) It is recommended that companies in the industry reference the Monte Carlo simulation method together with the accuracy analysis of the MSA Reference Manual [15] to determine the bias and linearity of the measurement systems when performing measurement system analysis. The simulation results can be used in line with the current business conditions to establish practical evaluation standards.

(3) After using the simulated Monte Carlo estimation model, results for the bias and linearity analysis for measuring system OG-04 were all below the 60% passing rate. After the initial assessment of the quality control department, it was determined that the poor accuracy may be due to the wear and tear of the probe, as well as the improper calibration of the high and low measurement range. It is suggested that for the implementation of Monte Carlo simulation accuracy analysis, if a measurement system cannot reach the 60% passing rate for bias or linearity, it should be considered that the measurement system has abnormalities in terms of accuracy variation. Immediate maintenance is recommended.

(4) Measurement System Analysis should be performed regularly. Meanwhile, in order to make effective use of the Measurement Systems Analysis results, relevant standards should be developed. By using the criteria configured in the Monte Carlo simulation, the capability of measurement systems should be classified. For the production management department, it can serve as a reference when conduct dispatching, and new product introduction. It prevents misuse of abnormal measurement tools. In addition, in terms of measurement systems, continuous improvement should be implemented, and measurement systems should be maintained to meet their requirements. This improves the calibration and managing system for measurement systems in companies.

(5) The Measurement System Analysis Guidelines can be used as a single threshold standard. However, with the proper use of simulation and estimation models, we can effectively identify the accuracy of measurement systems. We offer our study to companies that are currently using MSA for measurement systems analysis so that, in future, they can use it as a reference when performing accuracy analysis and developing practical standards for measurement systems.

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Author Contributions

Tsu-Ming Yeh outlined the manuscript and made substantial contributions to the design of this study. Fan-Yun Pai provided some core advice and checked the whole paper. Yung-Hsien Hung collected and analyzed the data. All authors have contributed to the manuscript equally, and all authors read and approved the final manuscript.

Conflicts of Interest

The authors declare no conflict of interest.

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