Minitab Case Study
Measurement System Analysis at a Medical Equipment Manufacturer

INTRODUCTION

This case study is about a Six Sigma project that was implemented by a supplier of medical equipment parts with the aim to reduce the total percentage of defective parts.

DEFINE

Problem:
A certain number of units of a specific part that is being manufactured for use in popular medical equipment sold to major hospitals are being scrapped due to inaccurate diameters or imperfections in shapes.
Objective:
Reduce the percentage of the defective medical equipment parts through Measurement System Analysis.

MEASURE

Before we measure the current performance of the process, we must ensure whether the system is efficient. In order to check the measurement system performance for part diameters, a random sample of 9 parts is taken, and two operators measure each of the 9 parts for two trials.

TABLE 12.1
Variable Data

Part	Operator	Diameter
8	1	9.013
2	1	9.012
1	1	9.014
4	1	9.013
3	1	9.012
9	1	9.012
5	1	9.013
6	1	9.010
7	1	9.013
9	2	9.012
4	2	9.013
7	2	9.013
1	2	9.014
6	2	9.010
5	2	9.012
3	2	9.012
2	2	9.011
8	2	9.013
6	1	9.010
1	1	9.014
2	1	9.011
5	1	9.012
7	1	9.013
8	1	9.013
4	1	9.013
3	1	9.012
9	1	9.012
4	2	9.013
6	2	9.010
7	2	9.013
9	2	9.012
2	2	9.012
1	2	9.014
3	2	9.012
8	2	9.013
5	2	9.013

Fig 1: Measurement System Data

To perform the Gage R&R study in Minitab, we go to Stat > Quality Tools > Gage Study > Gage R&R Study (Crossed). We select the “crossed” study as both the operators measured the same parts. In the Dialog Box that pops up, select “Part” for “Part Numbers”, “Operator” for “Operators”, and “Diameter” for “Measurement Data”. Click on “Gage Info” for the Gage Information dialog box to open. We enter the info as follows: Gage name – XYZ Calipers, Date of study – (Current Date), Reported By – (Name). Next we select “Options” and enter the following options in the dialog box: Alpha – 0.25, Select “Draw Graphs” and name the project with a suitable title. We then receive the following charts from the Gage Study.

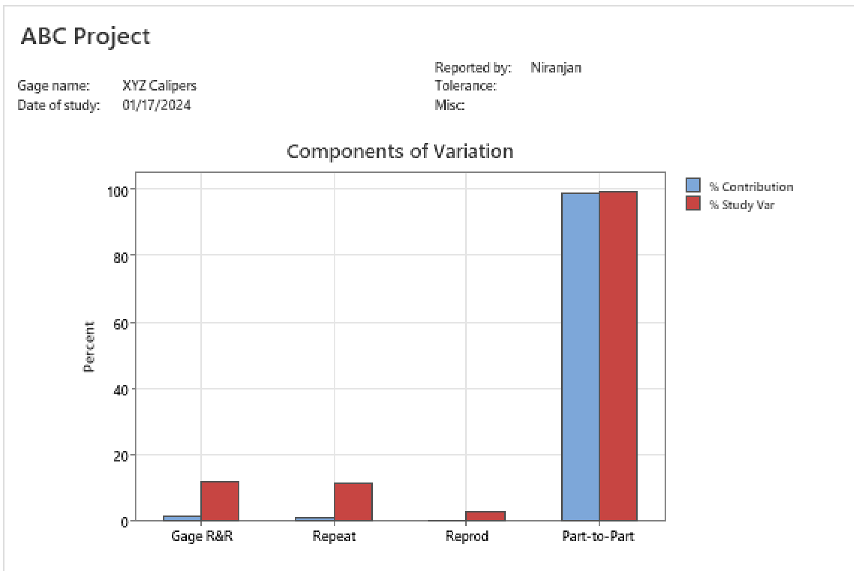

Fig 2: Components of Variation

It is evident from the above graph that most of the variation in the data is due to part-to-part variation. It is a good sign that the variation due to Gage R&R is very small. “% Contribution” measures the contribution to variance of the data and “% Study Var” measures the contribution to the standard deviation of the data.

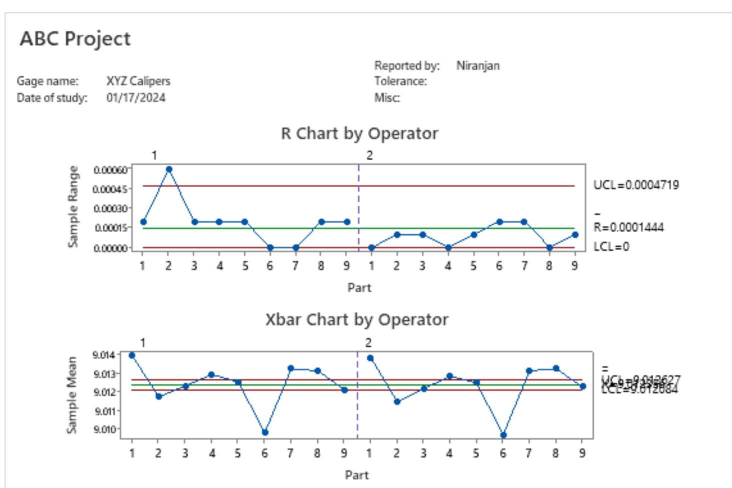

Fig 3: X Bar and R Charts

The above graphs show the X Bar (means) and R (ranges) charts. It is a good sign that the X Bar chart for each of the two operators is out of statistical control, because it shows that there is a lot of variation due to the difference among the parts. The X Bar charts are also identical with almost the same values for each part. This indicates good reproducibility, and that the measurement system is good. The low R bar value in the R Chart also means that the repeatability is good.

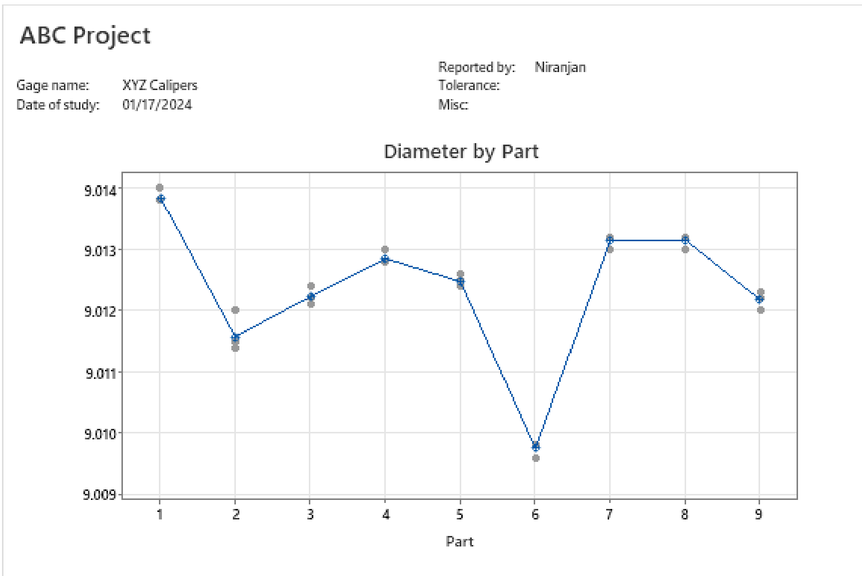

Fig 4: Diameter By Part

The above graph shows the X bar values of the two operators. The average values of these diameters are joined by straight lines. The X bar values are very close indicating good reproducibility for the measurement system.

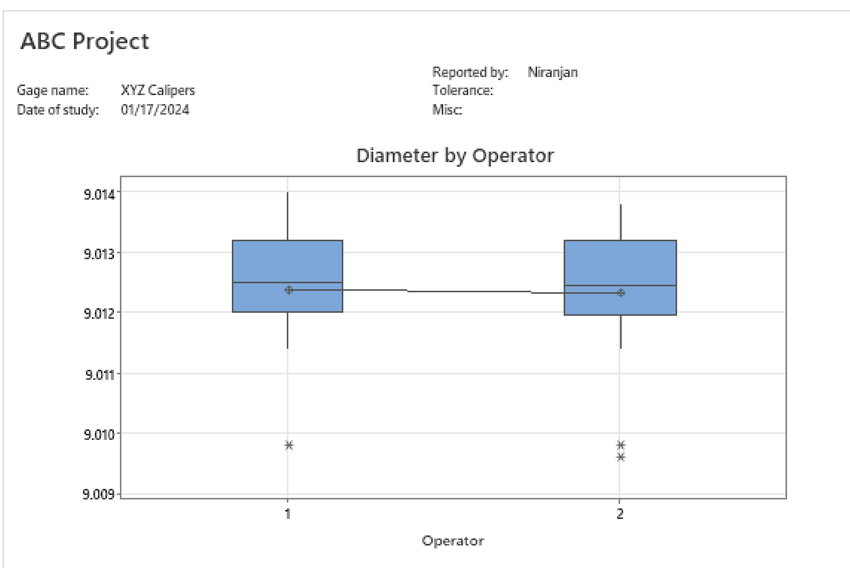

Fig 5: Diameter By Operator

The graph above also shows that the average diameters of all the parts for the two operators are almost equal, hence also indicating that the reproducibility of the measurement system is good.

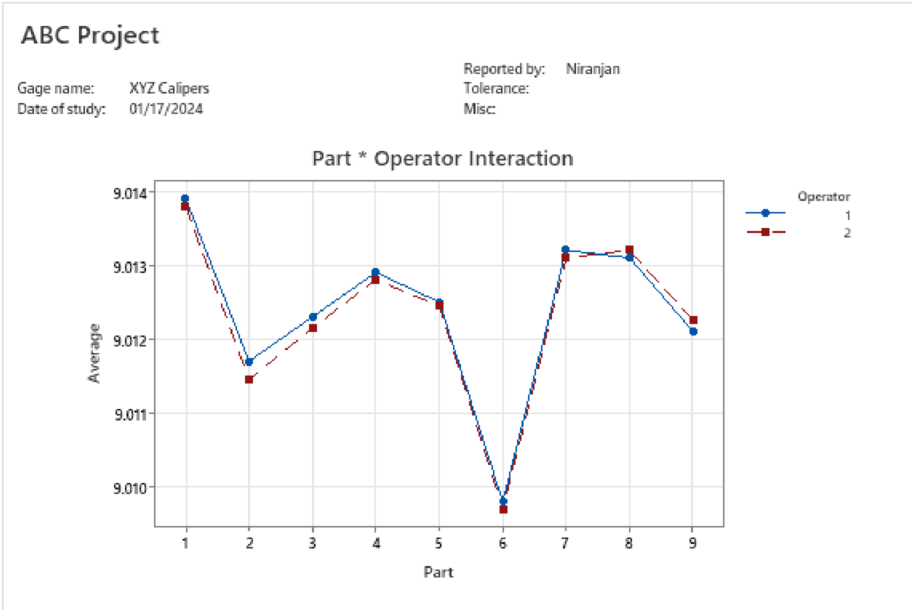

Fig 6: Part – Operator Interaction

The above-mentioned graph is essentially an overlap of the X bar charts of the two operators. Because the charts are almost parallel, it means that there is no significant interaction between the parts and the operators.

Two-Way ANOVA Table With Interaction

Source	DF	SS	MS	F	P
Part	8	0.0000448	0.0000056	373.407	0.000
Operator	1	0.0000000	0.0000000	2.667	0.141
Part * Operator	8	0.0000001	0.0000000	0.750	0.649
Repeatability	18	0.0000004	0.0000000		
Total	35	0.0000453			

α to remove interaction term = 0.25

Fig 7: ANOVA with Interaction

Two-Way ANOVA Table Without Interaction

Source	DF	SS	MS	F	P
Part	8	0.0000448	0.0000056	303.394	0.000
Operator	1	0.0000000	0.0000000	2.167	0.153
Repeatability	26	0.0000005	0.0000000		
Total	35	0.0000453			

Fig 8: ANOVA without Interaction

The P-value for part and operator interaction in Fig. 7 is 0.649 (>0.25). In Fig. 8, the P-value for Part is 0.00 (<0.05), and the P-value for Operator is 0.153 (>0.05). It is evident from this output that the variation in the diameters is due to the differences among parts and not due to variation between operators.

Variance Components

Source	VarComp	%Contribution (of VarComp)
Total Gage R&R	0.0000000	1.39
Repeatability	0.0000000	1.30
Reproducibility	0.0000000	0.08
Operator	0.0000000	0.08
Part-To-Part	0.0000014	98.61
Total Variation	0.0000014	100.00

Fig 9: Distribution of variances

Gage Evaluation

Source	StdDev (SD)	Study Var (6 × SD)	%Study Var (%SV)
Total Gage R&R	0.0001402	0.0008412	11.79
Repeatability	0.0001359	0.0008152	11.42
Reproducibility	0.0000346	0.0002075	2.91
Operator	0.0000346	0.0002075	2.91
Part-To-Part	0.0011814	0.0070883	99.30
Total Variation	0.0011897	0.0071380	100.00

Fig 10: Distribution of standard deviations

From the Distribution of variances, it is clear from the “%Contribution” values (variance values) that just 1.39% of the variation in the diameters is due to variation in gage repeatability and gage reproducibility. Fig. 10 gives us contribution to standard deviation of the data.

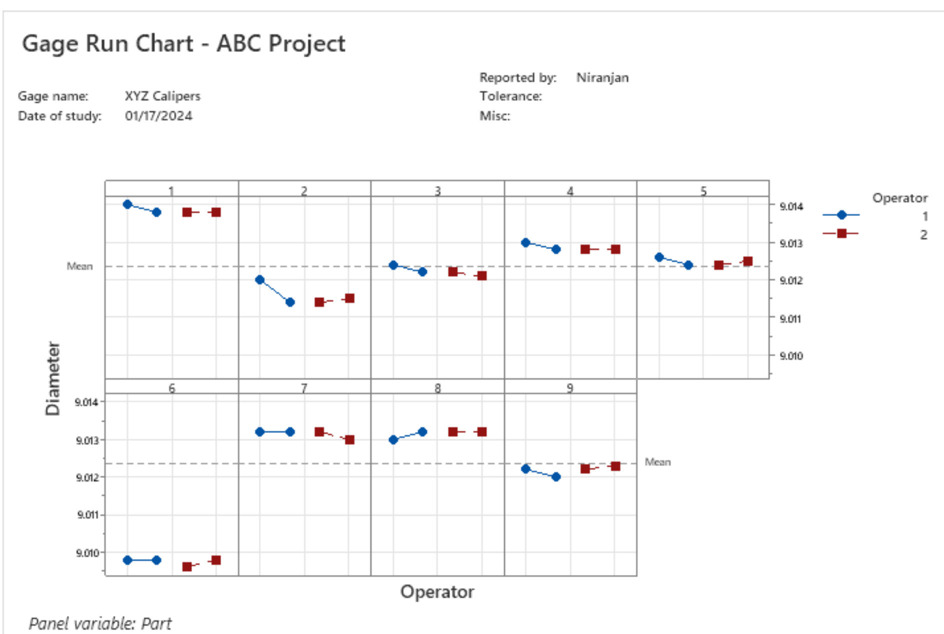

Fig 11: Gage Run Chart

It is clear from the gage run chart that the repeatability of each operator is good and the reproducibility between the two operators is good.

Next we proceed to ensure whether the system used to inspect the parts for “pass/fail” is efficient. Because this data is attribute, the procedure to evaluate the measurement system is different. Ten parts are randomly selected and each of the 3 operators (John, Mary, and Buddy) is asked to evaluate whether each part is “pass” or “fail”. This exercise is repeated for each operator (2 trials).

Attribute Data

Response	Part	Appraiser	Standard
Fail	6	John	Fail
Pass	7	John	Pass
Pass	10	John	Pass
Pass	8	John	Pass
Pass	2	John	Fail
Pass	4	John	Pass
Fail	1	John	Fail
Fail	9	John	Fail
Pass	3	John	Pass
Pass	5	John	Pass
Fail	9	Mary	Fail
Pass	5	Mary	Pass
Pass	8	Mary	Pass
Pass	10	Mary	Pass
Pass	7	Mary	Pass
Pass	3	Mary	Pass
Fail	2	Mary	Fail
Pass	4	Mary	Pass
Pass	1	Mary	Fail

(*Continued*)

Fig 12: Attribute Data

Attribute Data

Response	Part	Appraiser	Standard
Fail	6	Mary	Fail
Pass	3	Buddy	Pass
Pass	4	Buddy	Pass
Fail	2	Buddy	Fail
Fail	6	Buddy	Fail
Pass	5	Buddy	Pass
Fail	9	Buddy	Fail
Pass	8	Buddy	Pass
Pass	10	Buddy	Pass
Pass	7	Buddy	Pass
Fail	1	Buddy	Fail
Pass	3	John	Pass
Fail	6	John	Fail
Pass	5	John	Pass
Pass	8	John	Pass
Pass	4	John	Pass
Pass	7	John	Pass
Fail	1	John	Fail
Pass	10	John	Pass
Fail	9	John	Fail
Pass	2	John	Fail
Fail	6	Mary	Fail
Pass	3	Mary	Pass
Pass	4	Mary	Pass
Pass	10	Mary	Pass
Pass	5	Mary	Pass
Pass	7	Mary	Pass
Fail	2	Mary	Fail
Fail	1	Mary	Fail
Fail	9	Mary	Fail
Pass	8	Mary	Pass
Fail	1	Buddy	Fail
Fail	9	Buddy	Fail
Pass	10	Buddy	Pass
Fail	6	Buddy	Fail
Pass	4	Buddy	Pass
Pass	5	Buddy	Pass
Pass	8	Buddy	Pass
Pass	7	Buddy	Pass
Pass	3	Buddy	Pass
Fail	2	Buddy	Fail

Fig 13: Attribute Data (Contd.)

Next we go to Stat > Quality Tools > Attribute Agreement Analysis. Select “Response” for “Attribute column”, “Part” for “Samples”, “Appraiser” for “Appraisers”, and “Standard” for “Known standard/attribute”. Next we fill the information dialog box respectively.

Within Appraisers

Assessment Agreement

Appraiser	# Inspected	# Matched	Percent	95% CI
Buddy	10	10	100.00	(74.11, 100.00)
John	10	10	100.00	(74.11, 100.00)
Mary	10	9	90.00	(55.50, 99.75)

 # Matched: Appraiser agrees with him/herself across trials.

Fleiss’ Kappa Statistics

Appraiser	Response	Kappa	SE Kappa	Z	P(vs > 0)
Buddy	Fail	1.00000	0.316228	3.16228	0.0008
	Pass	1.00000	0.316228	3.16228	0.0008
John	Fail	1.00000	0.316228	3.16228	0.0008
	Pass	1.00000	0.316228	3.16228	0.0008
Mary	Fail	0.78022	0.316228	2.46727	0.0068
	Pass	0.78022	0.316228	2.46727	0.0068

Fig 14: Repeatability analysis for attribute data

It is evident from the table that Buddy and John are perfect with respect to repeatability, and Mary’s repeatability is 90%. Typically, 90% or over is considered acceptable for repeatability.

Between Appraisers

Assessment Agreement

# Inspected	# Matched	Percent	95% CI
10	8	80.00	(44.39, 97.48)

 # Matched: All appraisers’ assessments agree with each other.

Fleiss’ Kappa Statistics

Response	Kappa	SE Kappa	Z	P(vs > 0)
Fail	0.809524	0.0816497	9.91460	0.0000
Pass	0.809524	0.0816497	9.91460	0.0000

Fig 15: Reproducibility analysis for attribute data

The table above shows that the reproducibility of the system is 80%. Typically, 80%–90% is considered marginally acceptable for reproducibility.

Each Appraiser vs Standard

Assessment Agreement

Appraiser	# Inspected	# Matched	Percent	95% CI
Buddy	10	10	100.00	(74.11, 100.00)
John	10	9	90.00	(55.50, 99.75)
Mary	10	9	90.00	(55.50, 99.75)

 # Matched: Appraiser's assessment across trials agrees with the known standard.

Assessment Disagreement

Appraiser	# Pass / Fail	Percent	# Fail / Pass	Percent	# Mixed	Percent
Buddy	0	0.00	0	0.00	0	0.00
John	1	25.00	0	0.00	0	0.00
Mary	0	0.00	0	0.00	1	10.00

 # Pass / Fail: Assessments across trials = Pass / standard = Fail.
 # Fail / Pass: Assessments across trials = Fail / standard = Pass.
 # Mixed: Assessments across trials are not identical.

Fleiss' Kappa Statistics

Appraiser	Response	Kappa	SE Kappa	Z	P(vs > 0)
Buddy	Fail	1.00000	0.223607	4.47214	0.0000
	Pass	1.00000	0.223607	4.47214	0.0000
John	Fail	0.78022	0.223607	3.48925	0.0002
	Pass	0.78022	0.223607	3.48925	0.0002
Mary	Fail	0.89011	0.223607	3.98069	0.0000
	Pass	0.89011	0.223607	3.98069	0.0000

Fig 16: Accuracy analysis for attribute data

It is evident from the accuracy analysis that that Buddy's accuracy (percentage of times Buddy's responses matched with the standard responses) is 100%, John's accuracy is 90%, and Mary's accuracy is 90%. Typically, 90% or over is considered acceptable for accuracy.

All Appraisers vs Standard

Assessment Agreement

# Inspected	# Matched	Percent	95% CI
10	8	80.00	(44.39, 97.48)

 # Matched: All appraisers' assessments agree with the known standard.

Fleiss' Kappa Statistics

Response	Kappa	SE Kappa	Z	P(vs > 0)
Fail	0.890110	0.129099	6.89476	0.0000
Pass	0.890110	0.129099	6.89476	0.0000

Fig 17: Overall accuracy analysis for attribute data.

Finally the overall accuracy report (percentage of times the responses of all of the inspectors matched with the standard response) is 80%. Typically, 80%–90% is considered marginally acceptable for reproducibility. The kappa coefficients are 1.0 for performances of 100%. The better the performances are, the greater the Kappa coefficients are, with a maximum possible value of 1.0.

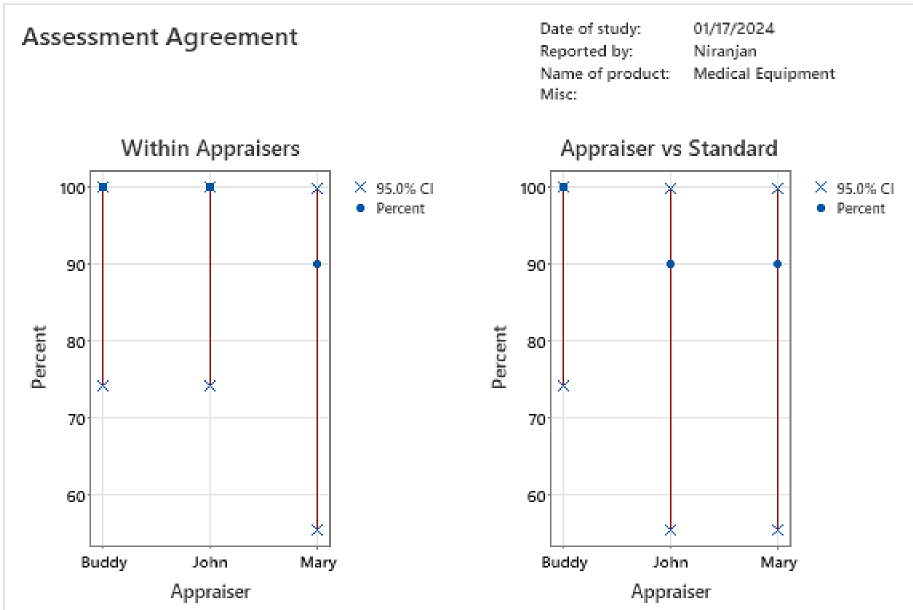

Fig 18: Confidence intervals for repeatability and accuracy for each appraiser

The figure above shows the confidence intervals for repeatability and individual accuracy of each inspector. The intervals are not so precise because of the small sample size of parts. Because the measurement system is at least marginally acceptable with respect to repeatability, reproducibility, individual accuracy, and overall accuracy, the quality head proceeds to get further samples to measure the current defects per million opportunities (DPMO) of the manufacturing process.

ANALYZE, IMPROVE AND CONTROL

Finally, upon brainstorming with the technicians and after a couple of inspections, it becomes clear that one of the five machines in the assembly line has a faulty motor coupler. Hence, the faulty motor coupler is replaced, and the process is improved. Confirmation of the improvement is made by recalculating the DPMO value. It is recommended that regular maintenance of the five machines in the assembly line be performed.