IE 508: Quality Assurance
Mini-Project 4: Tools of Quality
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Process in study – Monitoring blood sugar levels for a Type 2 Diabetic person

The process examined for this report pertains to the lifestyle of a newly diagnosed Type-2 diabetic. This report is not intended to diagnose or make any medical recommendations. **The purpose of this report is to monitor Bob's variation in blood sugar level.** Type 2 diabetes is a health condition developed when the body becomes resistant to insulin or the individual's pancreas does not produce sufficient insulin. Insulin is an essential biological substance used to help glucose move into cells. Therefore, when the body can't produce sufficient insulin, glucose builds up in the bloodstream.

This health condition requires type 2 diabetics to monitor their glucose-sugar-levels to help manage their diabetes. As summarized in Figure 2, Bob records his sugar level at 7 different times throughout the day. Bob's daily routine begins waking up and getting ready for the day. The first observation is recorded approximately at 6:30 am before he eats breakfast. At approximately 8 to 9 am, Bob records a second observation approximately 2 hours after breakfast. The third observation is recorded at 11:30 am, right before lunch, followed by the fourth observation recorded at approximately 1 to 2 pm (2 hours after lunch). The fifth measurement is recorded before dinner time, between 5:30 to 7 pm. The sixth observation is recorded 2 hours after dinner. The seventh observation is recorded at bedtime approximately at 10 pm. All observations are recorded using Blood Glucose Meter (Figure 1) that electronically stores observations for 5 days.

Bob has expressed his concern regarding taking 7 measurements throughout the day because it can be difficult to manage with his work schedule or any unforeseen events throughout the day. The data collected will be analyzed to review Bob's progress in managing his sugar level.

Figure 1: Blood Glucose Meter

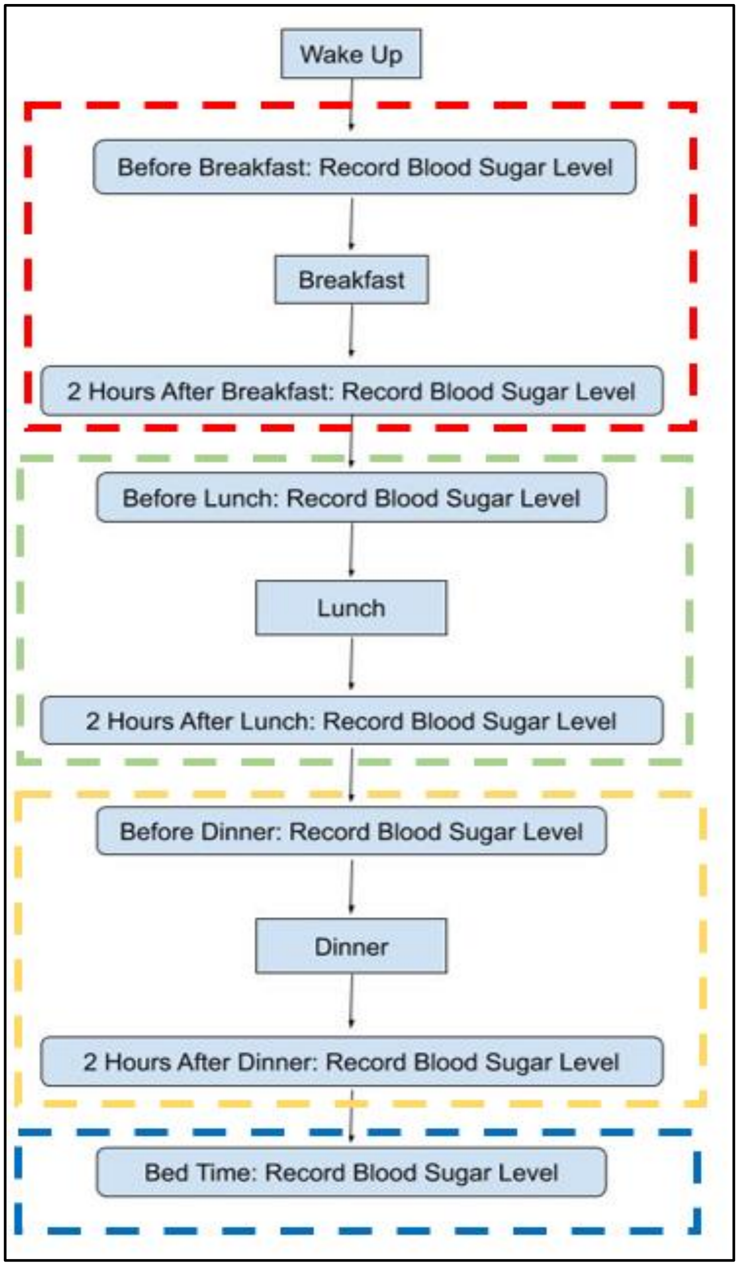

Figure 2: Process Flow Chart

Data Collection

Table 1 summarizes the data was retrieved from the history log in the glucose meter and the recommended range of sugar level for each measurement. For observations before a meal (breakfast, lunch, dinner), the recommended range is less than 180 mg/dl. The recommended range for 2 hours after a meal and before bed time is less than 180 mg/dl and 100-140 mg/dl respectively.

Table 1: Sugar Level Data for each observation from March 1st, 2020 to April 17th, 2020.

	Units: mg/dL						
	Breakfast		Lunch		Dinner		Bedtime
Date	Before (80-130)	2 Hours After (less 180)	Before (80-130)	2 Hours After (less 180)	Before (80-130)	2 Hours After (less 180)	(100-140)
3/1/2020	103	112	130	106	108	120	117
3/2/2020	95	116	120	116	104	114	129
3/3/2020	95	112	110	119	109	120	112
3/4/2020	110	120	105	99	119	131	120
3/5/2020	116	143	104	118	128	136	125
3/6/2020	104	110	123	104	121	125	128
3/7/2020	108	98	123	106	115	130	114
3/8/2020	112	125	102	123	108	119	129
3/9/2020	107	121	104	91	121	127	134
3/10/2020	108	140	132	107	120	107	123
3/11/2020	112	123	111	109	118	106	120
3/12/2020	107	123	124	129	123	113	105
3/13/2020	108	129	103	107	104	121	118
3/14/2020	116	128	111	96	132	102	120
3/15/2020	113	140	97	122	111	127	140
3/16/2020	109	128	123	109	101	132	127
3/17/2020	108	105	130	98	119	123	114
3/18/2020	91	112	114	108	116	127	133
3/19/2020	106	103	138	121	121	142	123
3/20/2020	111	116	128	112	132	120	140
3/21/2020	115	122	122	104	128	120	129
3/22/2020	131	113	120	92	104	129	132
3/23/2020	109	112	134	102	129	115	109
3/24/2020	112	123	118	114	131	101	125
3/25/2020	112	123	140	134	114	124	121
3/26/2020	133	130	114	133	121	107	121
3/27/2020	111	123	129	128	109	119	120
3/28/2020	118	142	102	119	125	130	119
3/29/2020	119	132	119	120	132	116	127
3/30/2020	128	130	143	127	137	107	139
3/31/2020	111	128	120	140	120	140	121
4/1/2020	110	157	143	136	108	125	133
4/2/2020	122	132	132	118	131	138	152
4/3/2020	95	118	140	104	137	140	136
4/4/2020	103	123	129	109	120	129	120
4/5/2020	117	138	132	144	119	135	118
4/6/2020	129	131	162	126	132	140	121
4/7/2020	110	129	140	149	123	125	106
4/8/2020	127	123	134	131	145	117	121
4/9/2020	121	129	126	140	138	104	123
4/10/2020	126	151	153	130	161	182	140
4/11/2020	94	108	99	125	118	115	104
4/12/2020	119	130	115	129	112	128	116
4/13/2020	89	114	101	114	109	123	103
4/14/2020	113	120	102	125	125	101	114
4/15/2020	117	109	110	132	121	132	121
4/16/2020	110	121	106	101	113	104	109
4/17/2020	130	103	113	134	117	102	113

Data Analysis

The objective for the Quality tools is to find whether the sugar level measurement process is adequate and it will give us a better control on the sugar levels in Bob's blood. The tools of quality applied are used in the following order:

1) Process Map
2) Histograms
3) Control Charts
4) Cause and Effect Diagrams or Fishbone Diagram/ 5Whys

Process Map

This tool was used to express knowledge of the process with the respective flow and potential control points.There are basically three symbols from the process flow chart method applied in the process map:

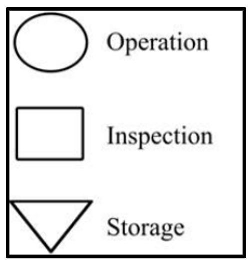

Figure 3: Key symbols for Process Map

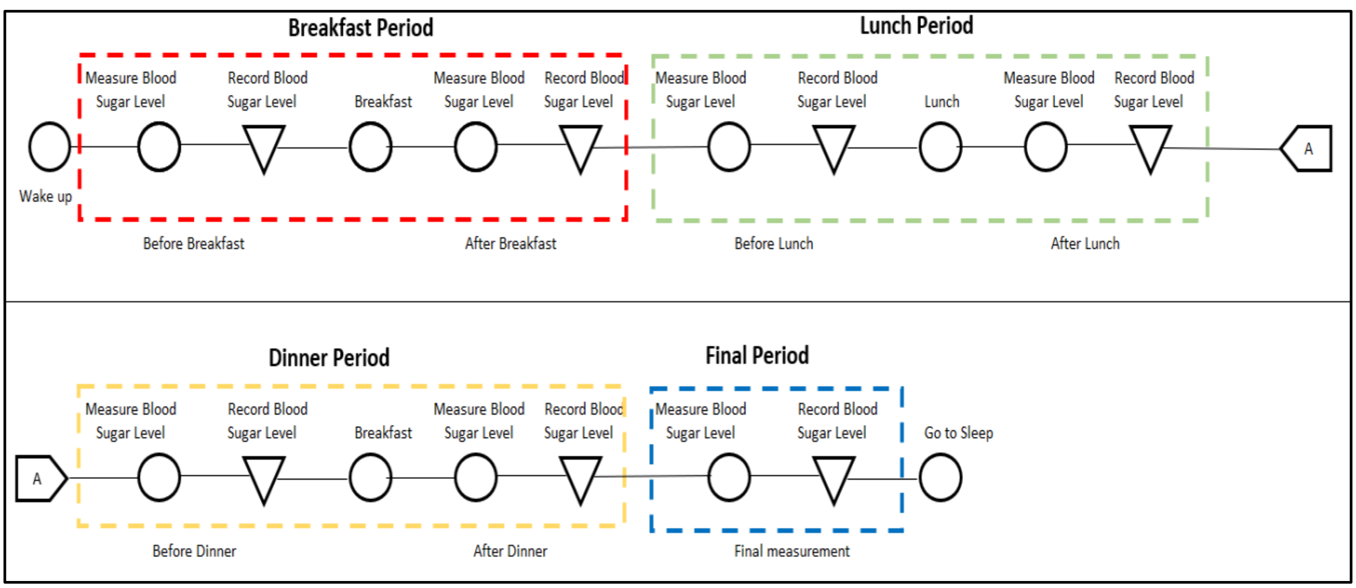

Figure 4: Process Map

The blood glucose level measurement process and record for the current process flow chart will be considered as operations and storage symbols. We use storage symbols for the record operation since Bob is taking notes in his notebook and storing the data accordingly. The initial process map is based on a schedule during a standard day.

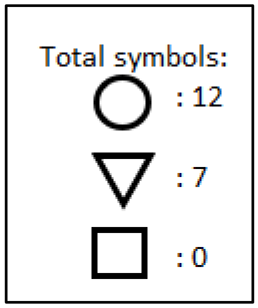

Figure 5: Symbols for Process Map

As we have stated there are no inspection processes, where Bob verifies if the data has been correctly recorded

Histograms

Histograms are a useful quality tool t**o analyze the variation in observed values** over time. In this case, plotting the observed sugar level values for different time periods helps us determine whether the observed values meet the target specifications, understand the process variation if any, and consequently work on the defects or shortcomings.

In order to have histograms with reliable interpretable results:

1. The sample data size should be 20 and above
2. The data should be randomly selected.

Histograms help us **understand the central tendency of observed values**. The tail ends of our histograms are essential since they tell us about the **uncertainties (risks) associated with our sample data**.

The histogram is divided into 18 bins which is approximately equal to the square-root of total number of observations (336). The width of bins is equal to the ratio of range and number of bins.

Numerical observations:

Observations	Meal	Central tendency	Target range
Before	Breakfast	(100, 115)	(80, 130)
	Lunch	(100, 140)	
	Dinner	(110, 130)	

After	Breakfast	(120, 130)	< 180
	Lunch	(105, 135)	
	Dinner	(110, 130)	
Bed-time	None	(115, 130)	(100, 140)

The histograms help us visualize the central tendency of observed values which provides a good baseline estimation about the measurement system accuracy. In this case, we observe that the sugar level values at different time periods are normally distributed and that the sugar level is in the target range. The standard deviation (10 to 15) is reasonable in all cases considering the nature of observed values.

In addition to this, we could analyze the abnormalities in observed values, track them to their specific time period and further improve the process/ take requisite precautions if needed. The frequency of values in tail ends is very low which suggests that Bob's sugar levels are in control.

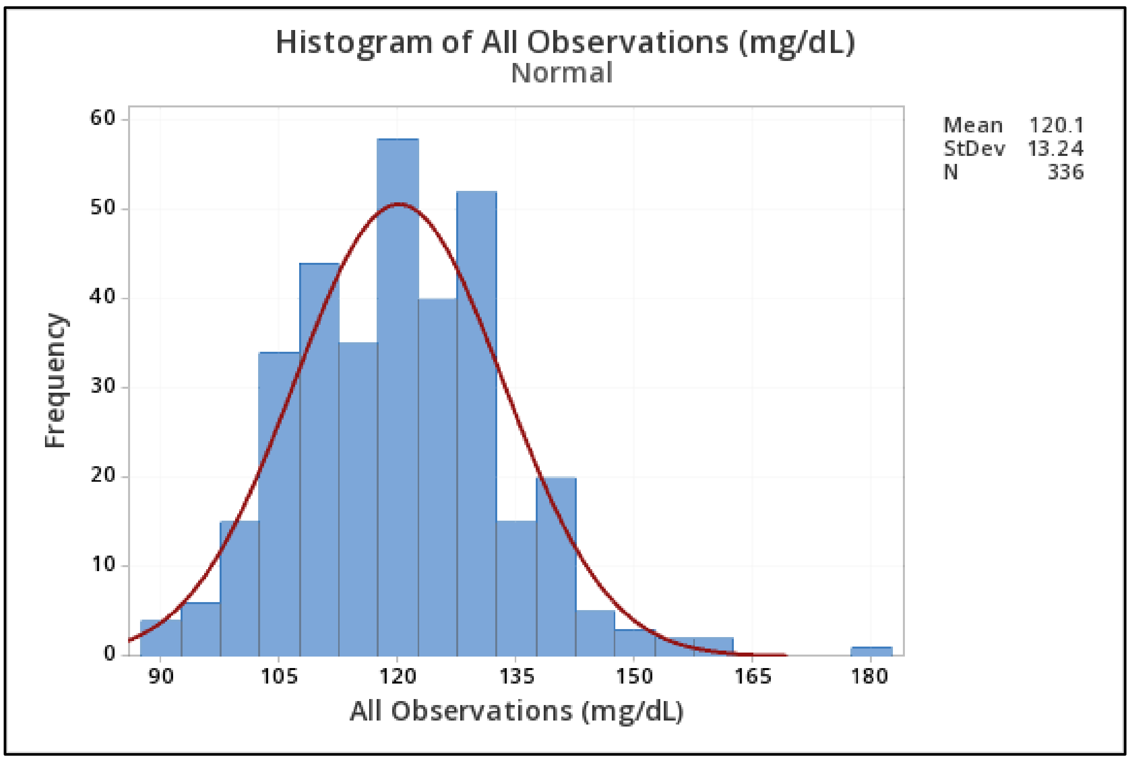

Figure 6: Histogram of all the observations collected with normal fitted curve

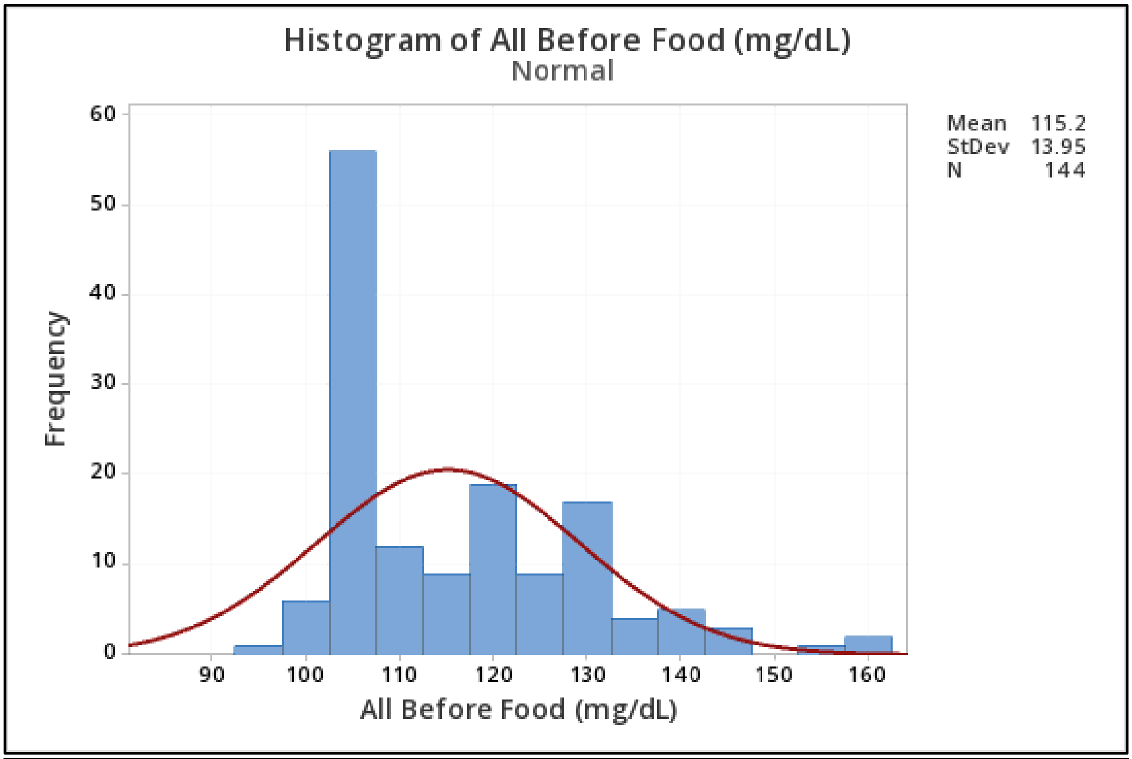

Figure 7: Histogram of all the observations collected before food (Breakfast, Lunch & Dinner) with normal fitted curve

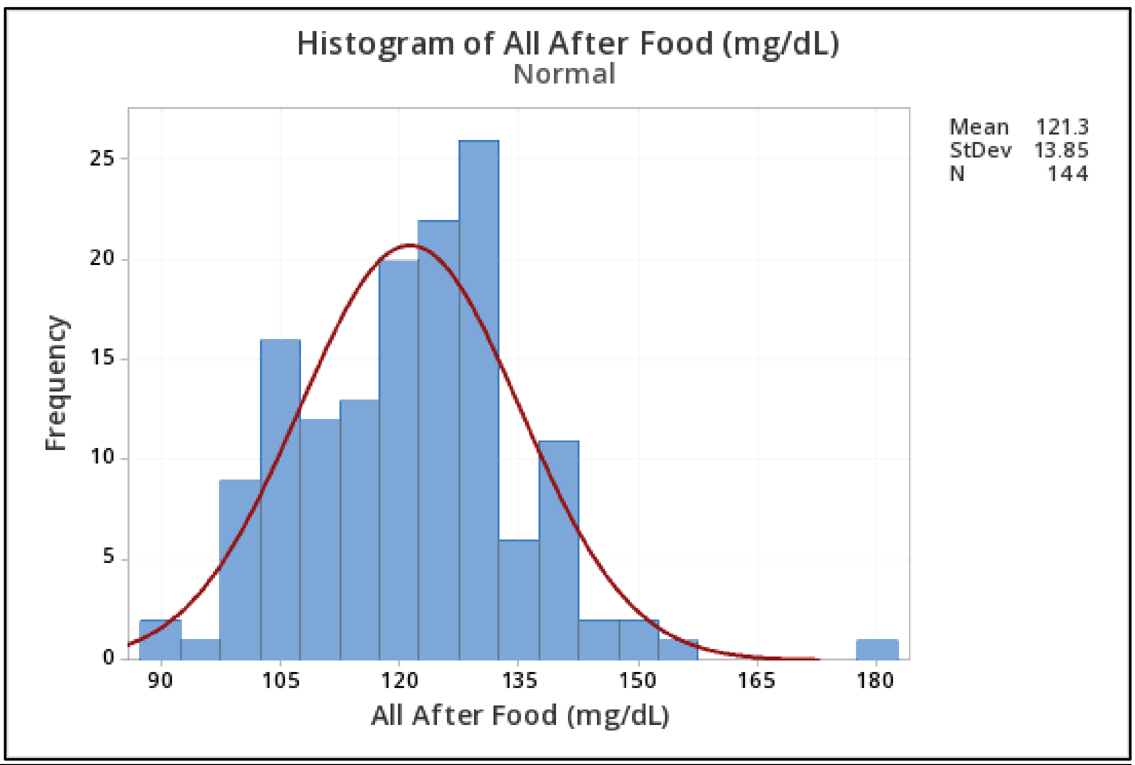

Figure 8: Histogram of all the observations collected after food (Breakfast, Lunch & Dinner) with normal fitted curve

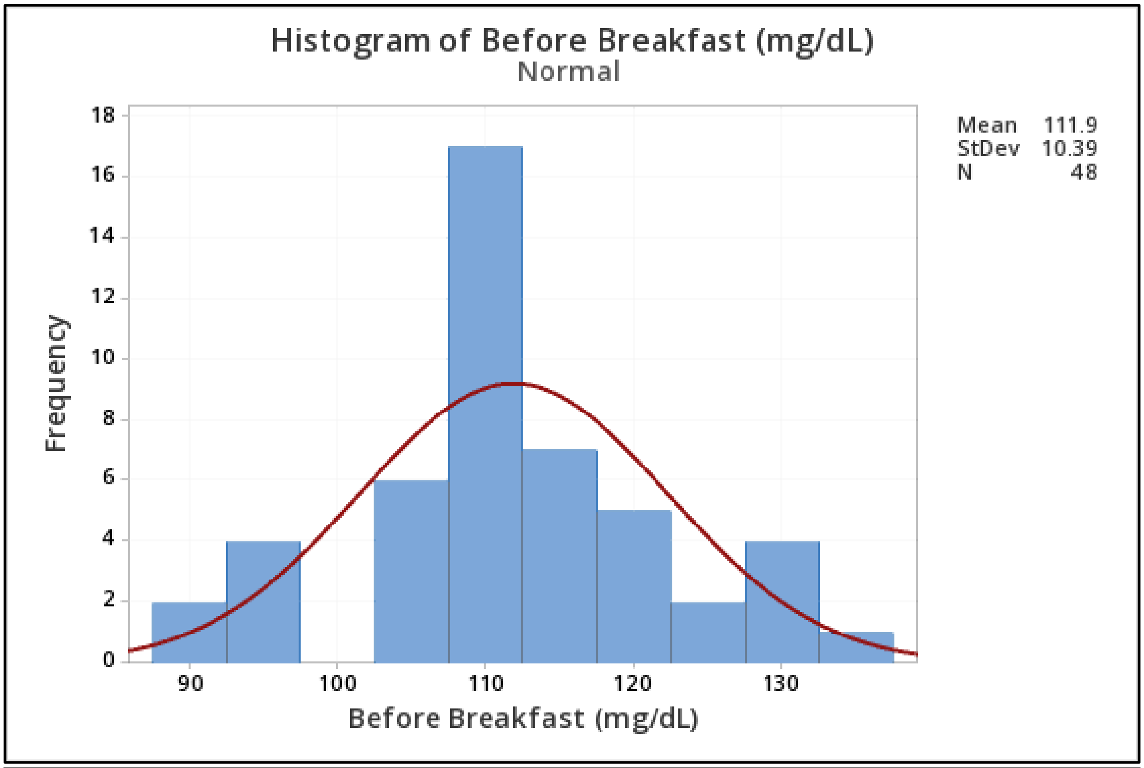

Figure 9: Histogram of all the observations collected before breakfast with normal fitted curve

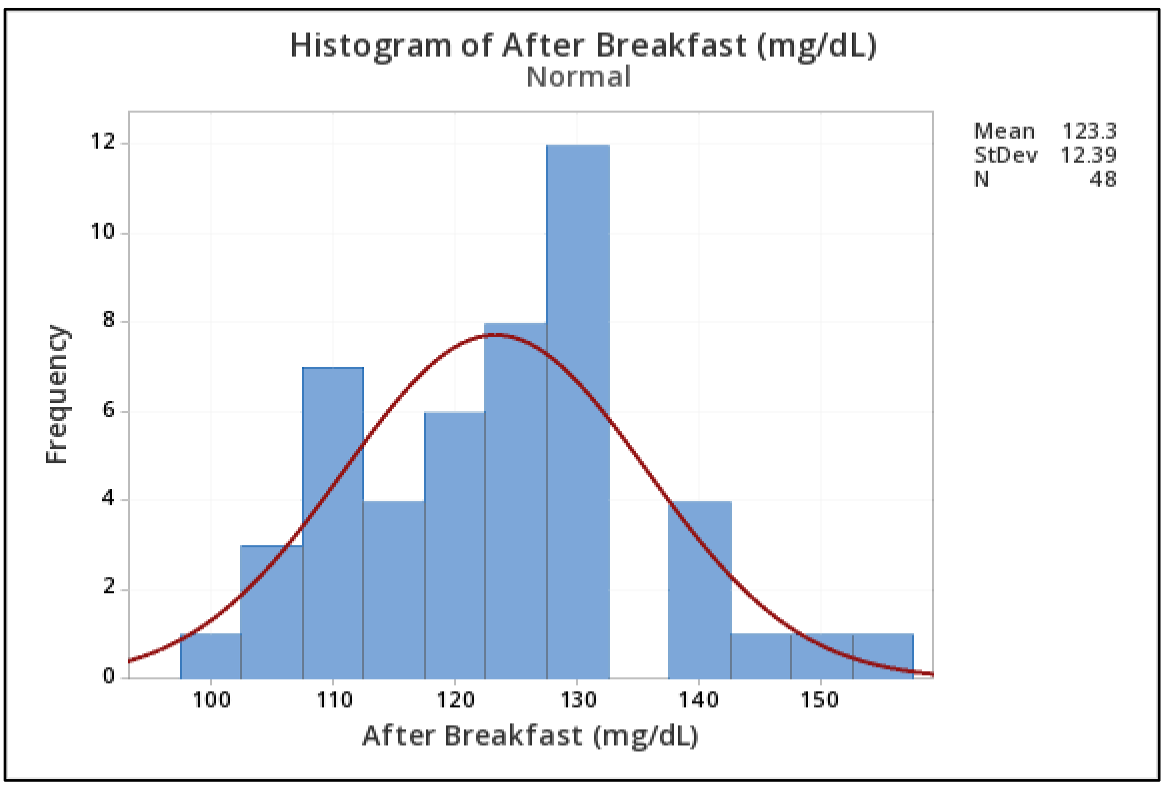

Figure 10: Histogram of all the observations collected after Breakfast with normal fitted curve

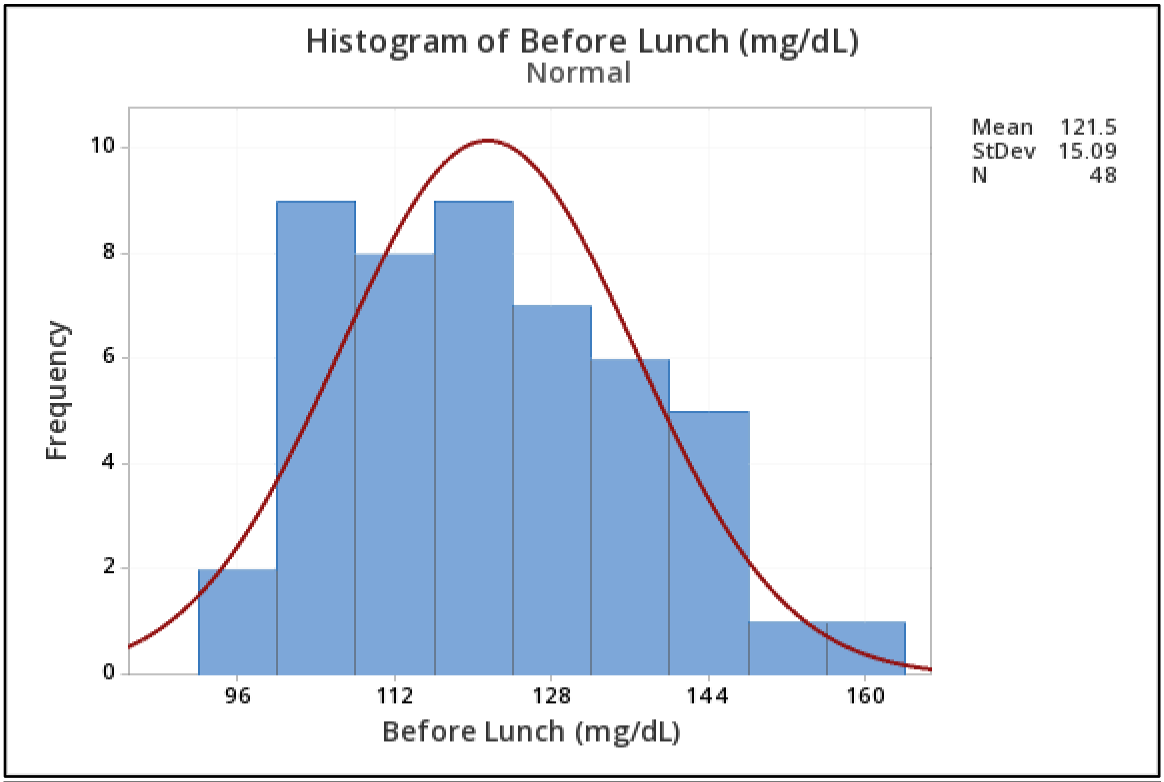

Figure 11: Histogram of all the observations collected before Lunch with normal fitted curve

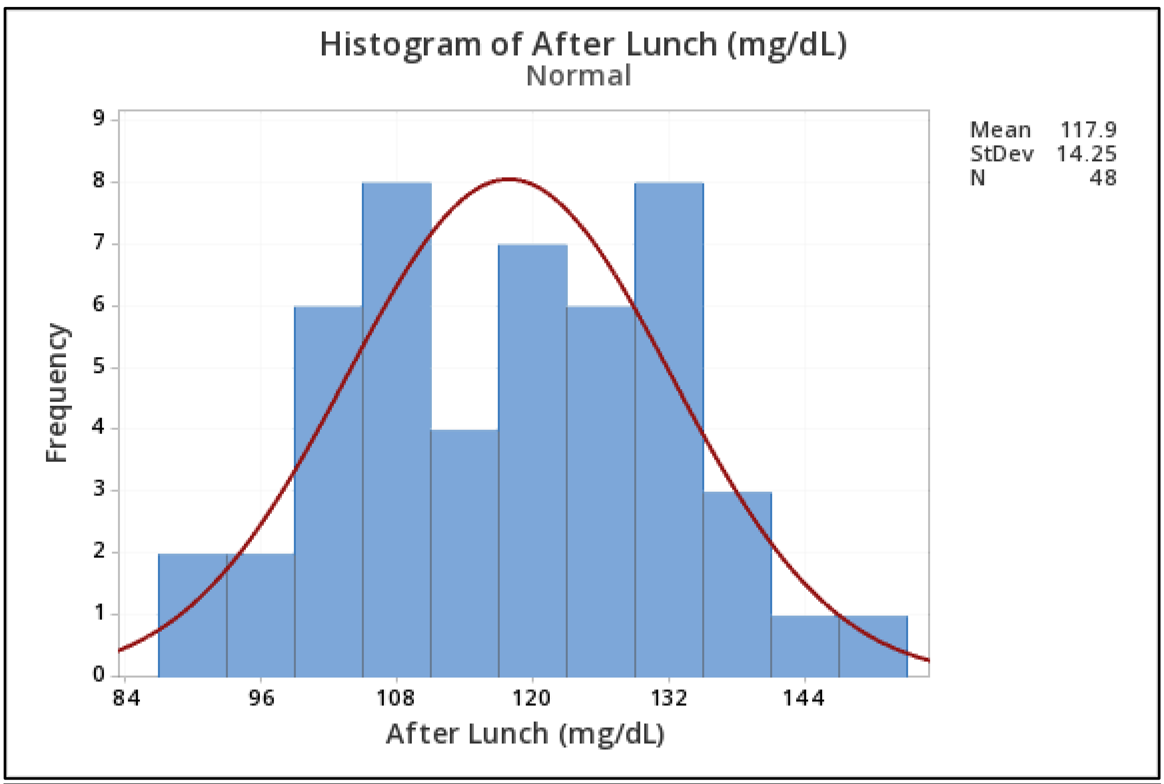

Figure 12: Histogram of all the observations collected after Lunch with normal fitted curve

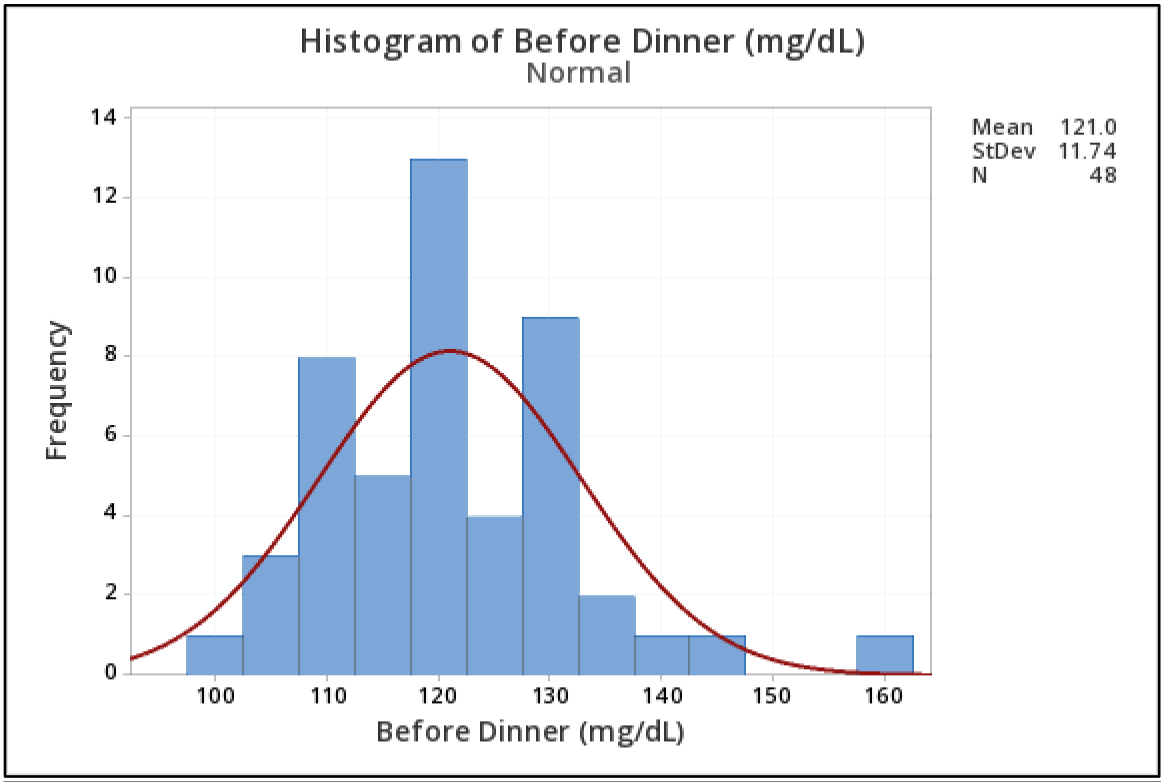

Figure 13: Histogram of all the observations collected before Dinner with normal fitted curve

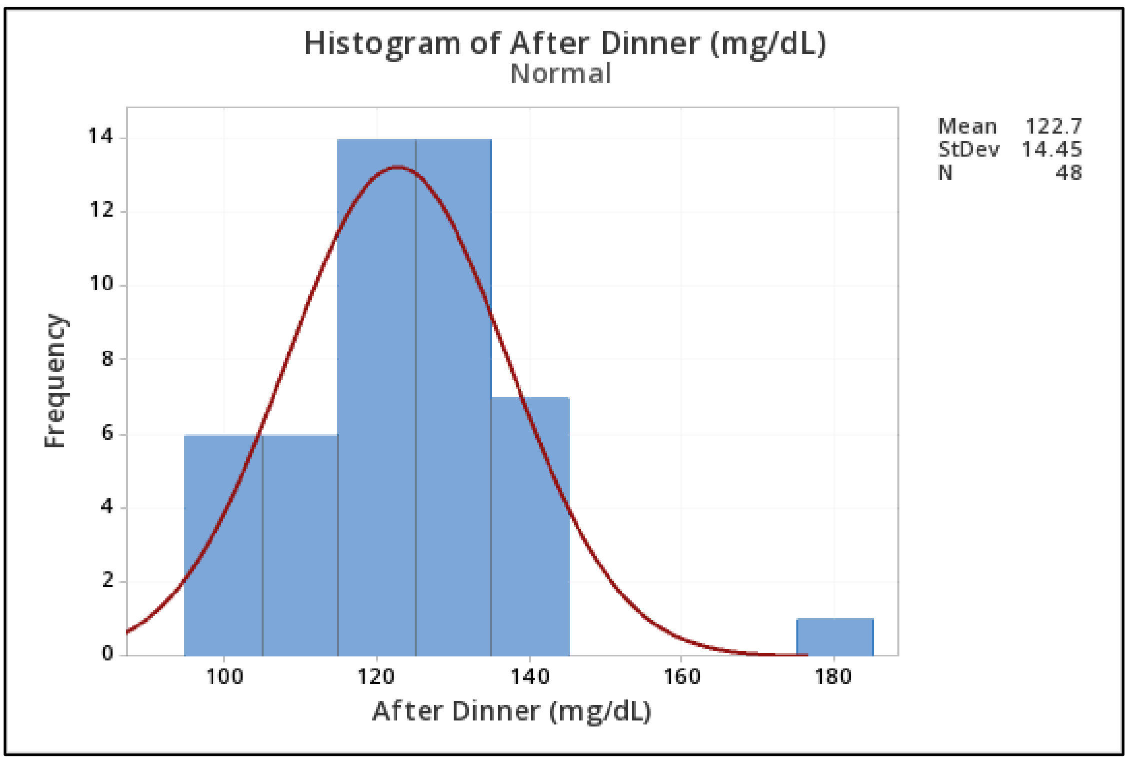

Figure 14: Histogram of all the observations collected after Dinner with normal fitted curve

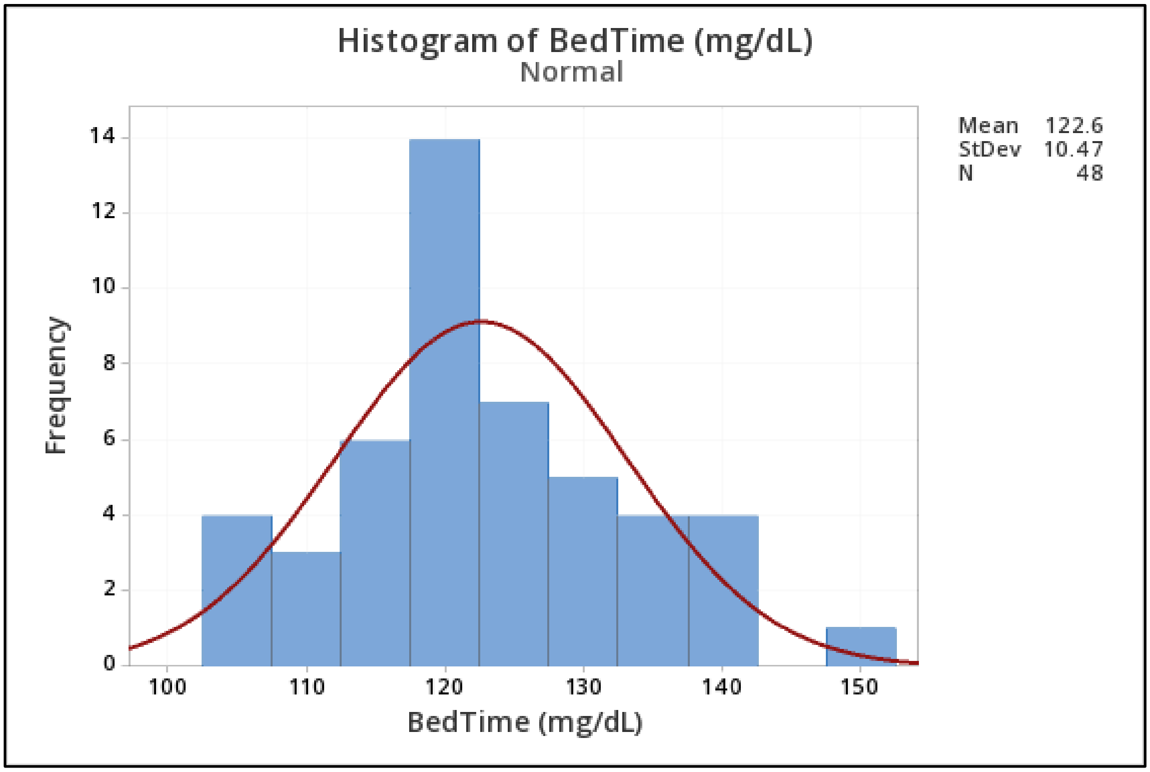

Figure 15: Histogram of all the observations collected at Bedtime with normal fitted curve

<u>Control Charts</u>

Individual (I) and moving range (MR) charts for moving range were created to monitor the process mean and variation for the continuous observations. Charts were created for observations before breakfast, after breakfast, before lunch, after lunch, before dinner, after dinner, at bedtime, and a summary of all observations.

<u>*All Observations*</u>

The I-MR chart for all observations is illustrated in Figure16 with a mean range of 14.35 mg/dL and standard deviation within equal to 12.718. It is observed that 2 points are more than 3 standard deviations above the centerline in the MR chart, suggesting the variation may not be stable. Point 219 and 232 refers to the observations recorded after lunch on 4/1/2020 and 232 on 4/3/2020. No unusual variation was identified; therefore the 2 points were not omitted from the data.

The I-chart suggests that the mean may not be stable with mean of 120.12 mg/dL and overall standard deviation of 13.237 mg/dL. Points 12, 13, 23-26 failed test 2 because of a shift in mean, whereas points 255, 285, and 286 were outside control limits. Another important observation from the I-chart is that most points after observation number 200 seem to be closer to or above the centerline. This observation cannot be validated since the figure summarizes all 336 data points; therefore the visual shift is minimal.

Figure 17 illustrates the I-MR chart if Special-Cause variation had been identified and the

2 data points omitted from the data. The figure suggests process variation is stable with mean range equal to 14.21 mg/dL and standard deviation within equal to 12.598 mg/dL. The I-chart, with the omitted points, suggests the process may not be stable with mean 120.09 mg/dL and overall standard deviation 13.049 mg/dL. Here, points 253, 283, 284 were outside the control limits and points 12, 13, 23-26 failed test 2 for a shift in mean.

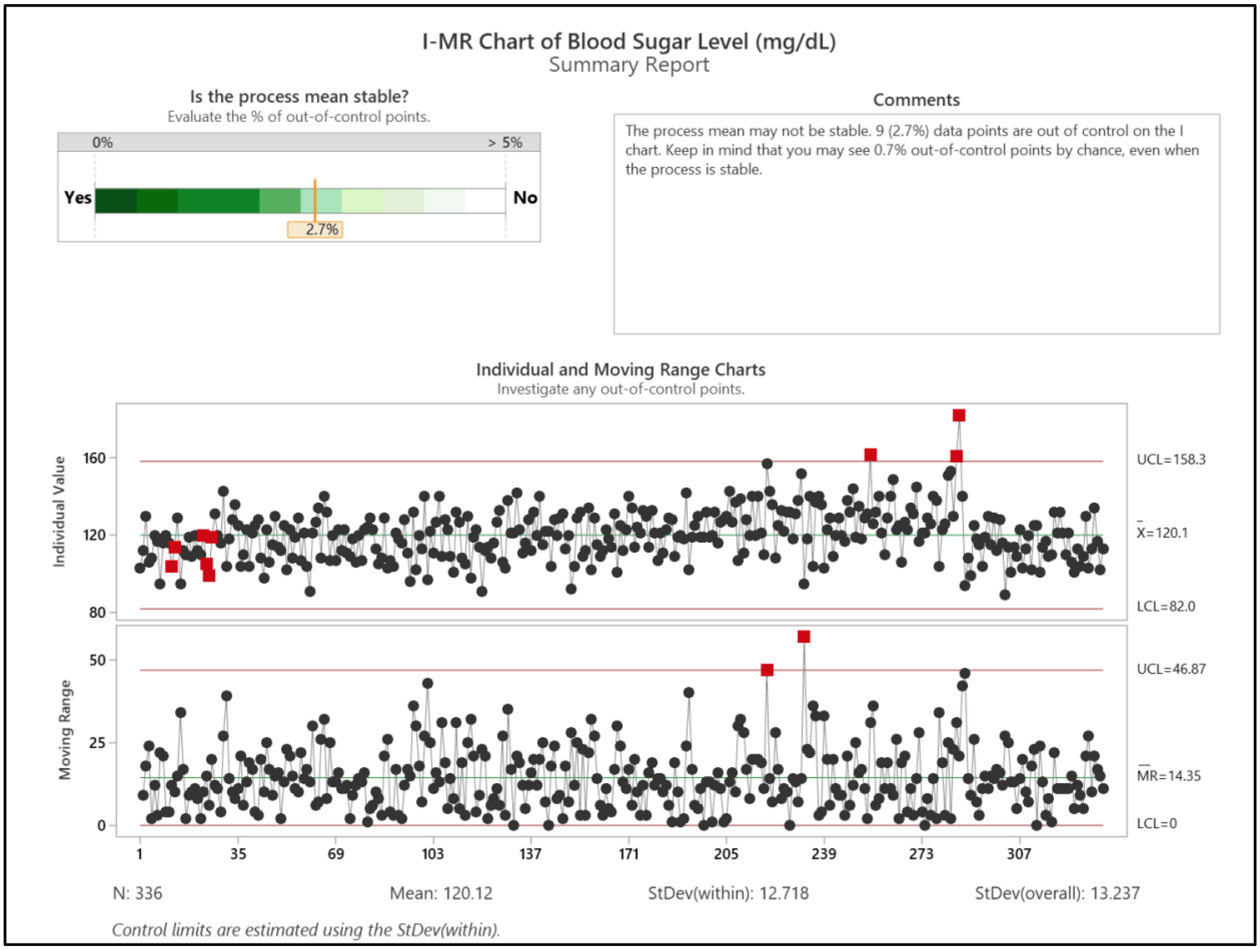

Figure 16: I-MR Chart of Blood Sugar Level for All Observations

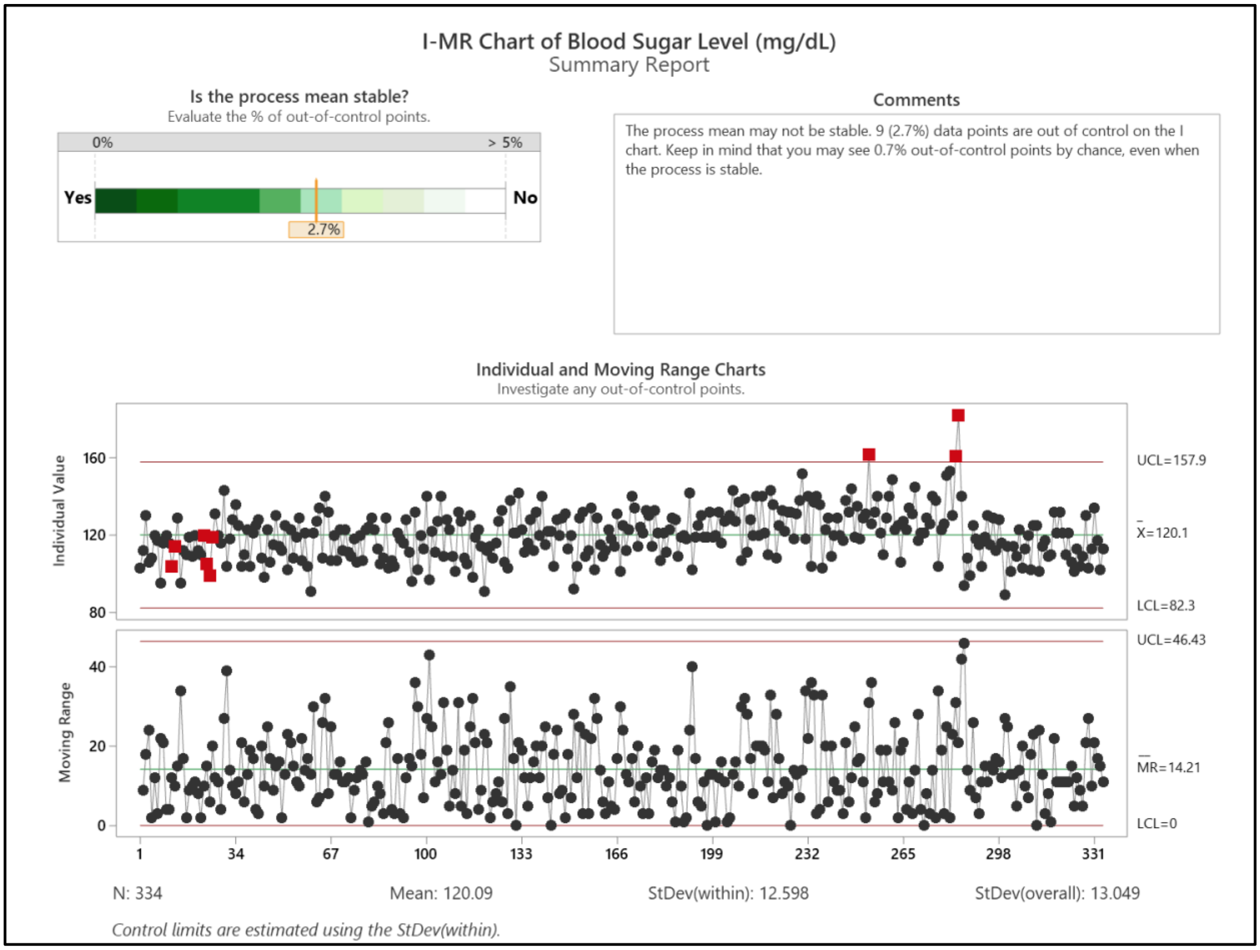

Figure 17: I-MR Chart of Blood Sugar Level with Data Points 219 and 232 Omitted

Before Breakfasts

The I-MR chart for observations before breakfast are illustrated in Figure 18. The MR chart suggests the variation in observations may be stable, with a mean range of 10.70 mg/dL and standard deviation within equal to 9.4877 mg/dL. The I-chart suggests the mean may be stable with mean 111.88 mg/dL and overall standard deviation of 10.389 mg/dL.

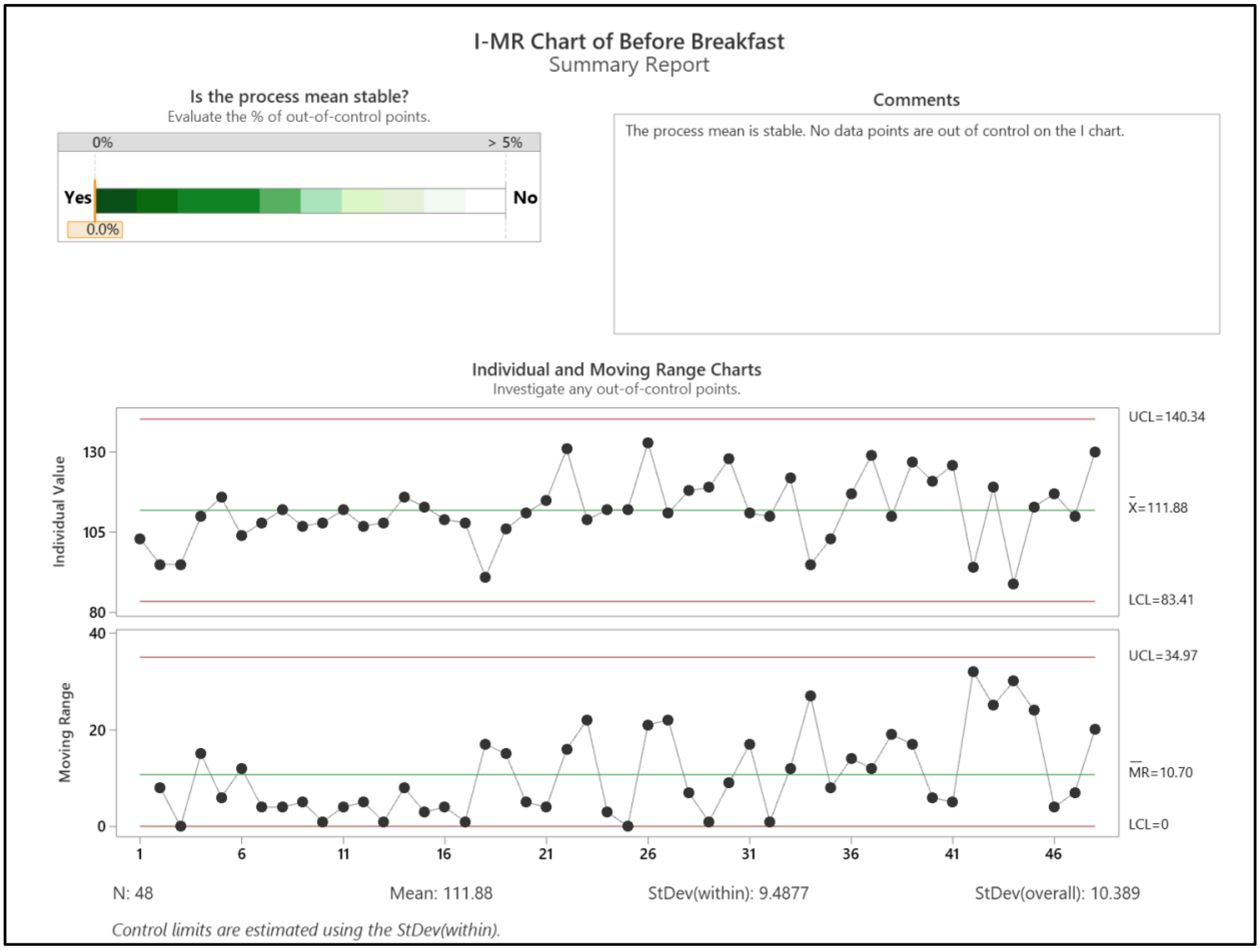

Figure 18: I-MR Chart of Blood Sugar Level Before Breakfast

After Breakfast

The MR chart in Figure 19 suggests that the process variation may not be stable, with mean range 12.06 mg/dL and standard deviation within equal to 10.695 mg/dL. Point 42 failed test 1 for being outside the control limits. However, no unusual cause was determined to have influenced the variation on April 11, 2020.

The I-chart suggests the mean may not be stable with mean 123.29 mg/dL and overall standard deviation of 12.389 mg/dL. Point 32 fell outside control limits and point 25 failed test 2 for a shift in mean.

Figure 20 illustrates the I-MR chart with data point 42 omitted from the data. The I-chart, with the omitted points, suggests the process variation is stable but the mean may not be stable. The process mean range obtained was 11.37 mg/dL and standard deviation within equal to 10.079 mg/dL. The process mean obtained was 123.62 mg/dL and overall standard deviation equal to 12.314 mg/dL. From the I-chart, we can observe that point 32 failed test 1 (out of control limits) and point 25 failed test 2.

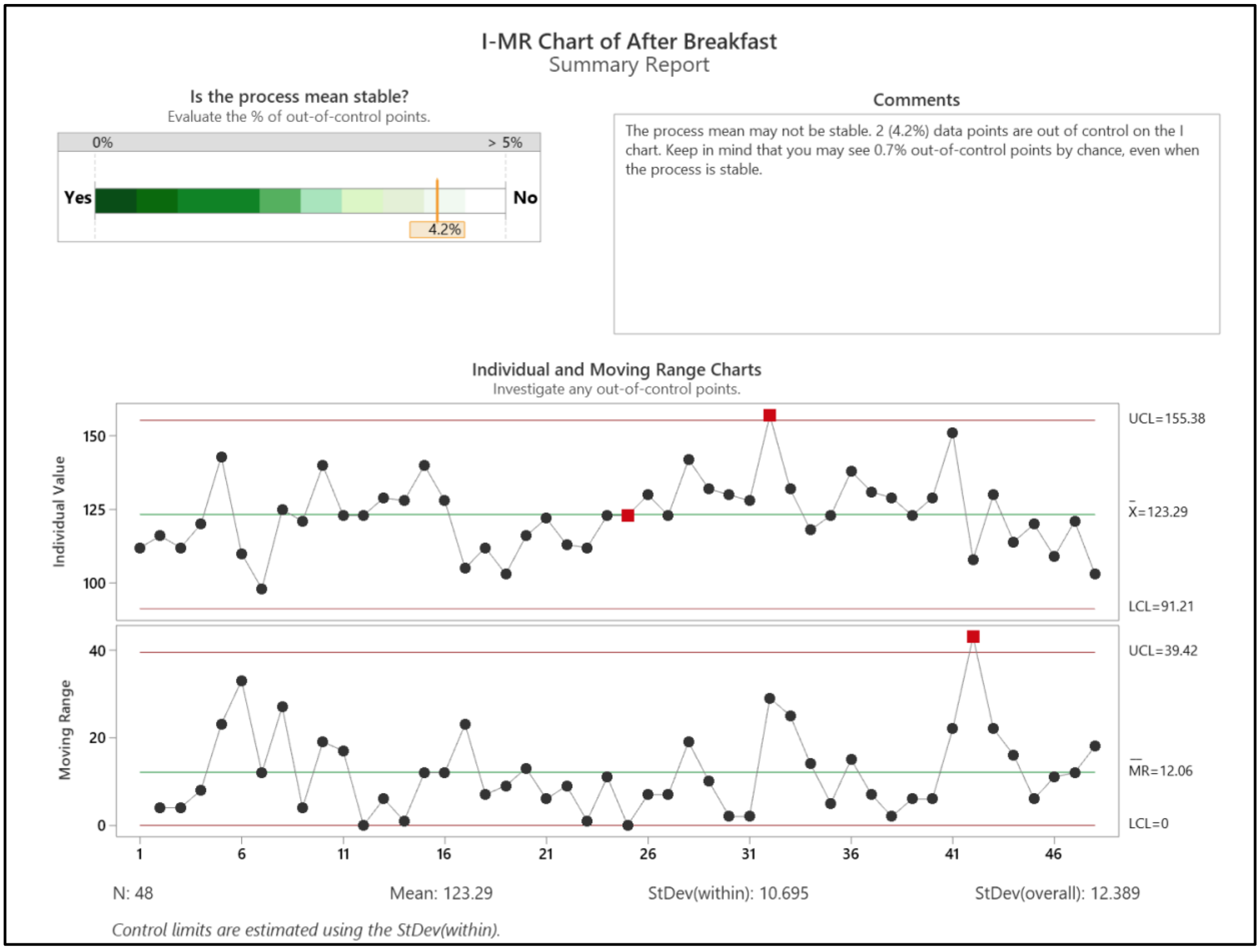

Figure 19: I-MR Chart of Blood Sugar Level 2 Hours After Breakfast

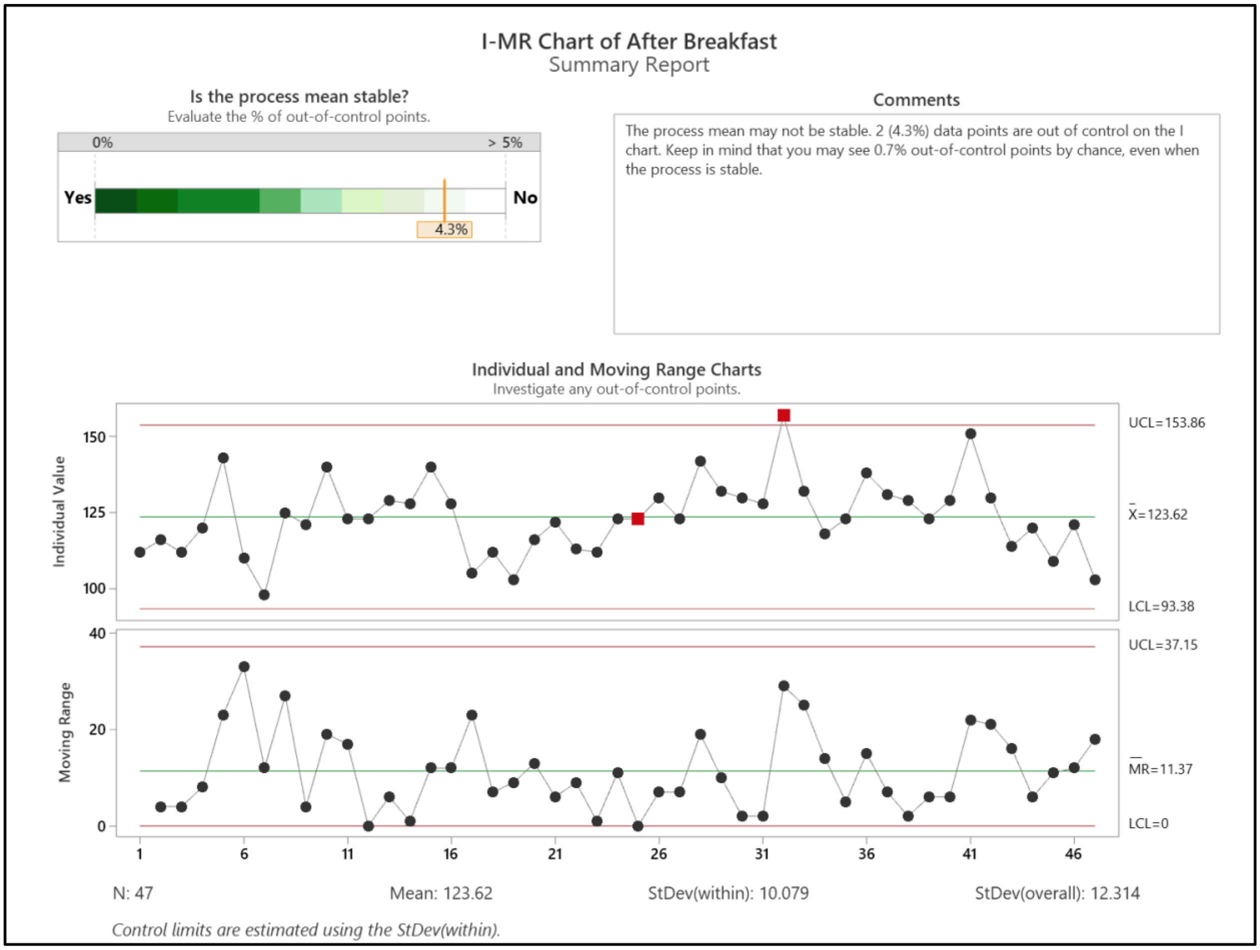

Figure 20: I-MR Chart of Blood Sugar Level 2 Hours After Breakfast with Point 42 Omitted

Before Lunch

The I-MR chart for observations before lunch are illustrated in Figure 21. The MR chart suggests that the process variation may not be stable with point 42 out of control. The mean range is 14.91 mg/dL and standard deviation within equal to 13.222 mg/dL. However, no special-cause variation was determined to have influenced the variation on April 11, 2020.

The I-chart suggests the mean may not be stable with mean 121.46 mg/dL and overall standard deviation of 15.091 mg/dL. Point 37 failed test 1 because it 3 standard deviations away from the centerline. Points 40 and 41 failed test 2 for a shift in mean.

Figure 22 illustrates the I-MR chart with data point 42 omitted from the data. The I-chart, with the omitted points, suggests the process variation is stable but the mean may not be stable. The mean range calculated is 14.54 mg/dL and standard deviation within equal to 12.893 mg/dL. The process mean obtained is equal to 121.94 mg/dL and overall standard deviation 14.833 mg/dL. From the I-chart we can see that again point 37 failed test 1 (out of control limits) and points 40-41 failed test 2.

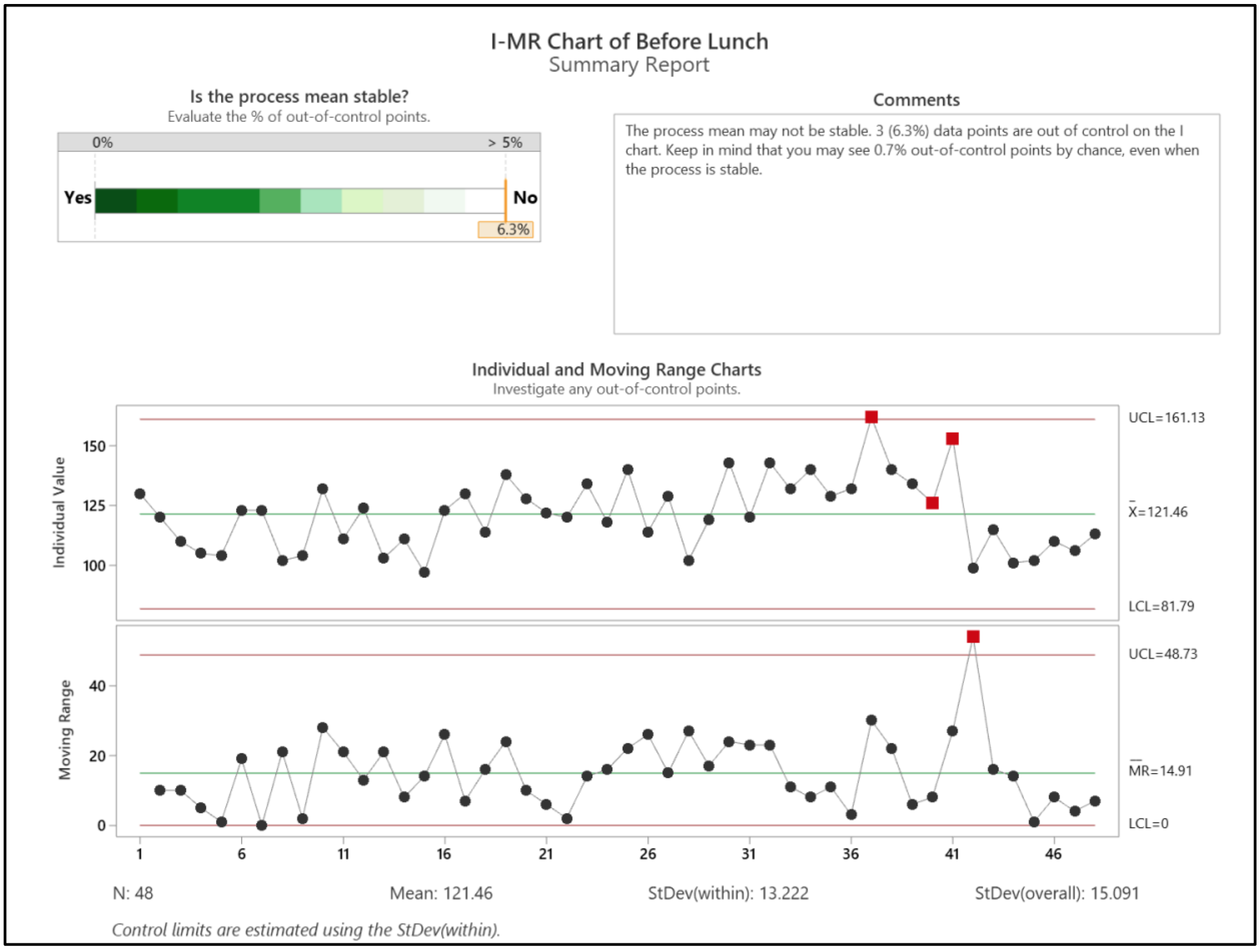

Figure 21: I-MR Chart of Blood Sugar Level Before Lunch

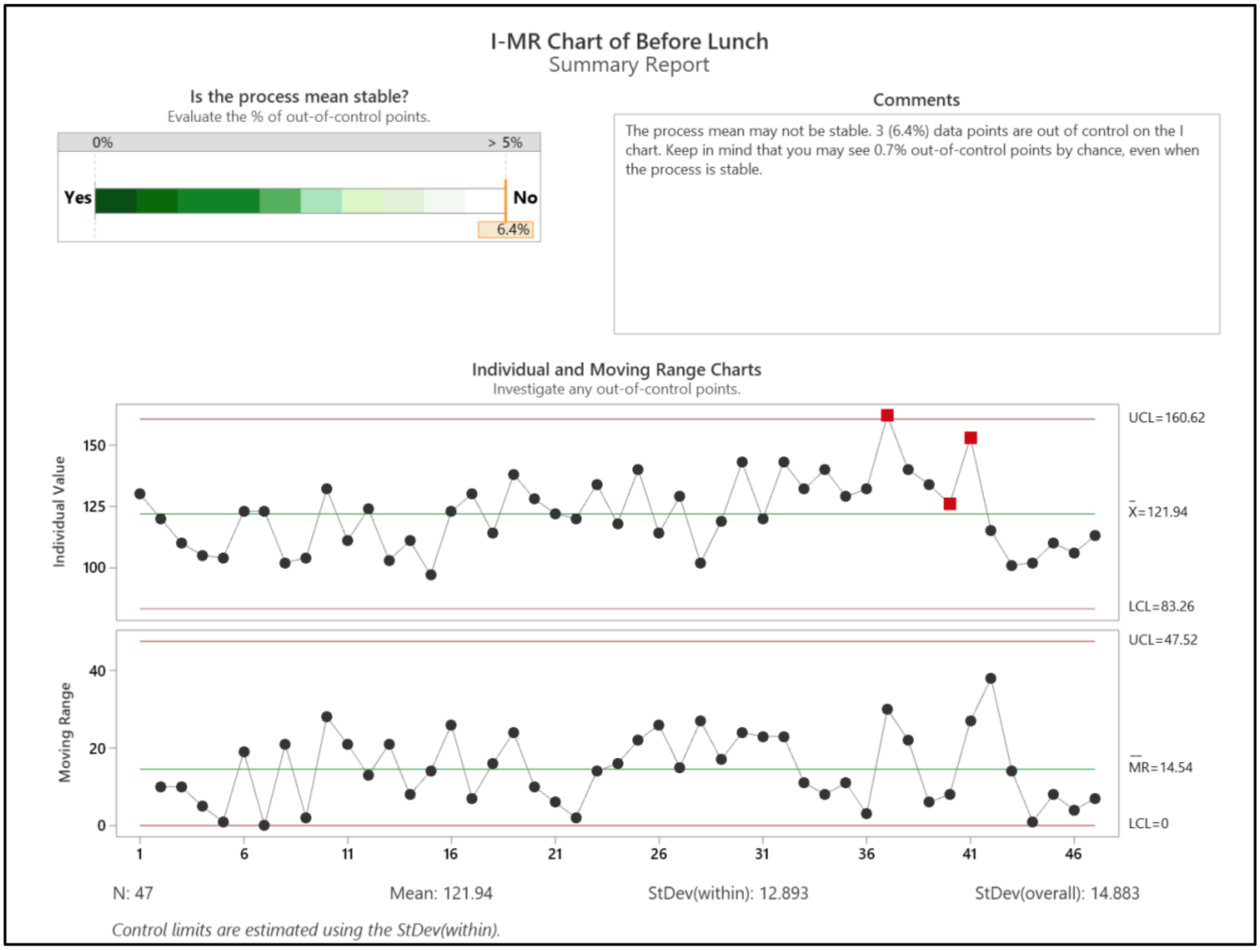

Figure 22: I-MR Chart of Blood Sugar Level Before Lunch with Data Point 42 Omitted

After Lunch

The MR chart in Figure 23 suggests that the process variation is stable. No points are out of control on the MR chart. In MR chart, mean range 13.36 mg/dL and standard deviation within equal to 11.845 mg/dL. Point 33 failed test 1 for being outside the control limits in the I chart. However, no special cause was determined to have influenced the variation.

The I-chart suggests the process may not be stable with mean 117.92 mg/dL and overall standard deviation of 14.250 mg/dL.

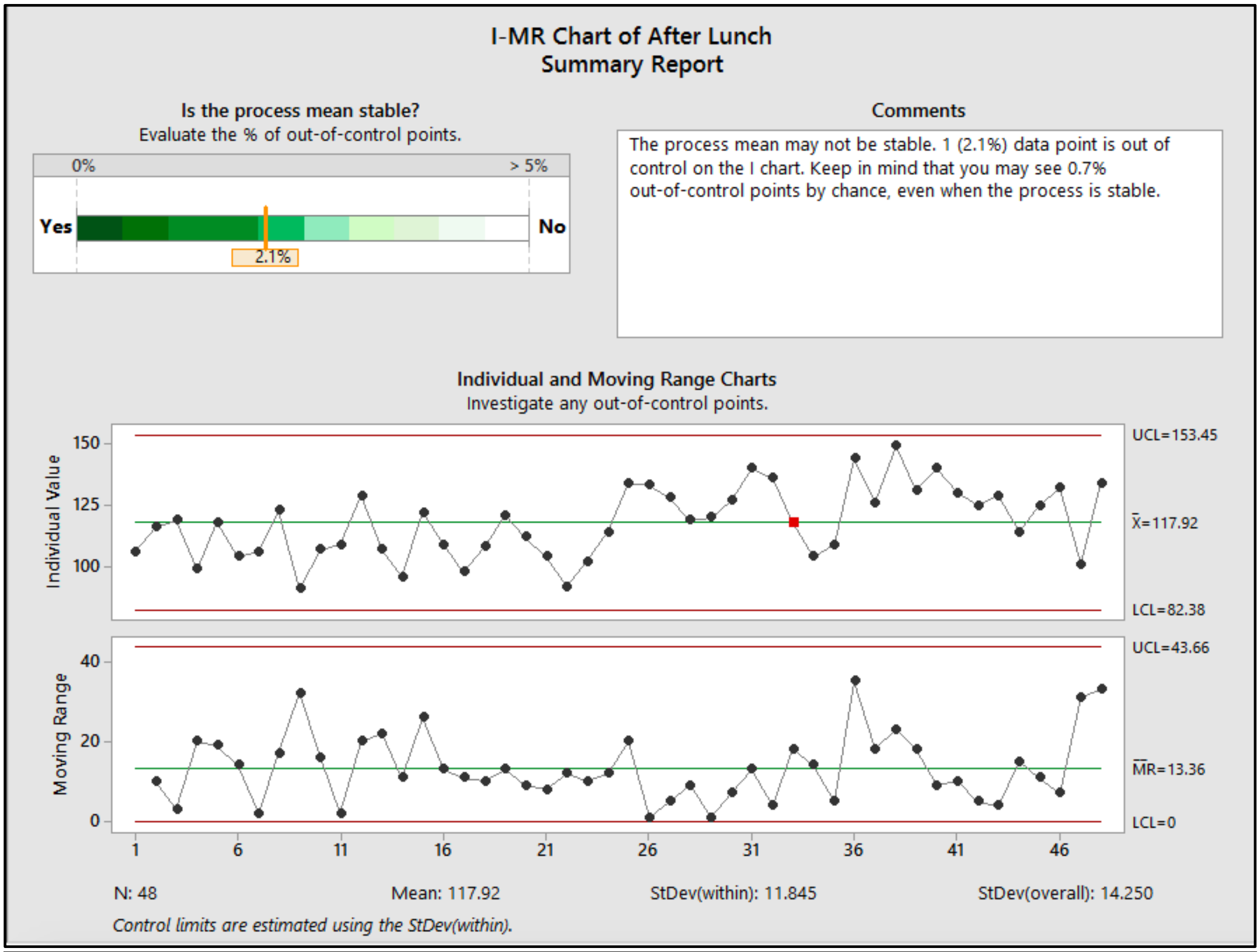

Figure 23: I-MR Chart of Blood Sugar Level After Lunch

Figure 24 illustrates the I-MR chart with data point 33 omitted from the data. The I-chart, with the omitted points, suggests the process variation is stable but the mean may not be stable. In the MR chart, the process mean range obtained was 14.49 mg/dL and standard deviation within equal to 12.843 mg/dL. The process mean obtained was 115.51 mg/dL and overall standard deviation equal to 14.352 mg/dL.

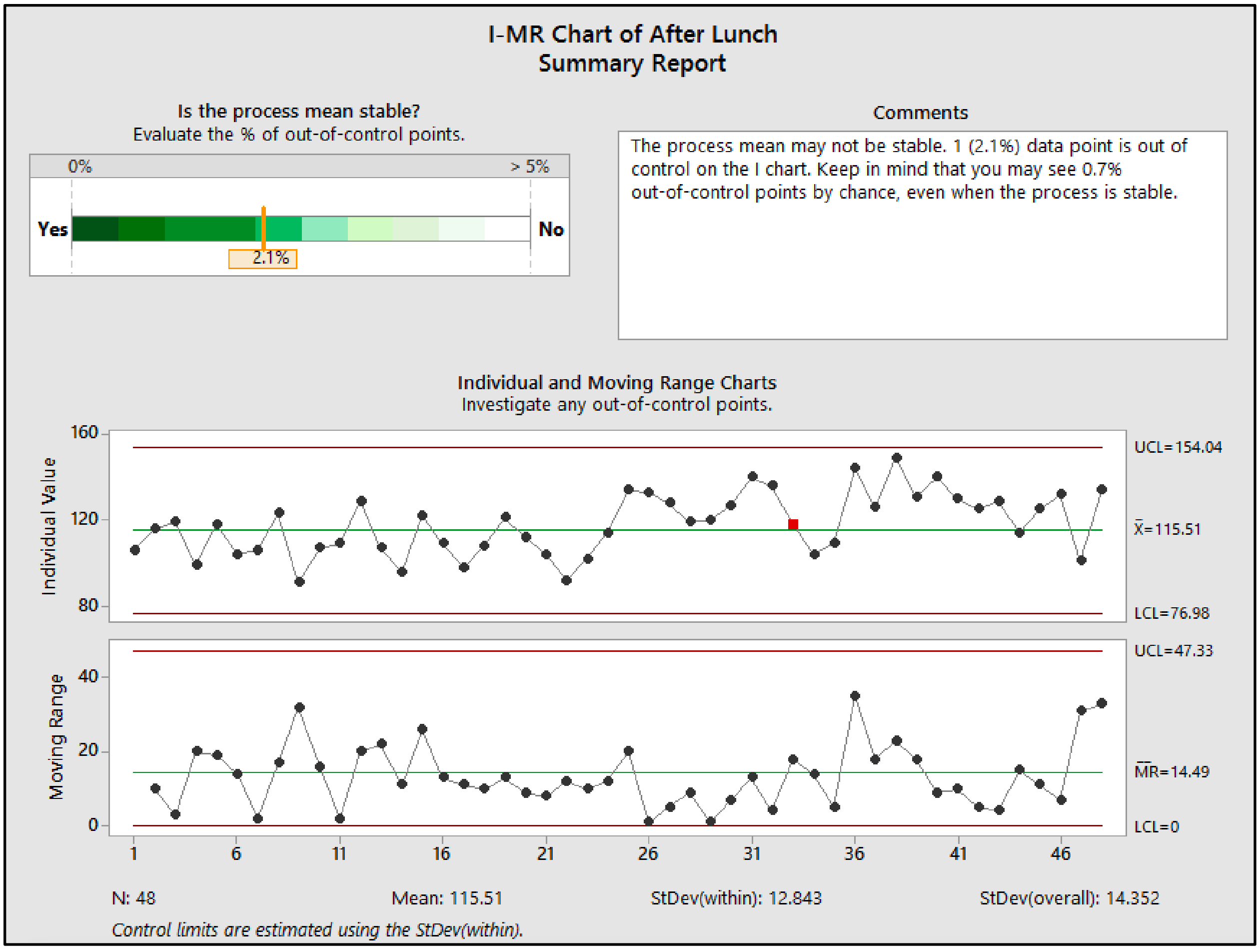

Figure 24: I-MR Chart of Blood Sugar Level After Lunch with Data Point 33 Omitted

Before Dinner

The MR chart in Figure 25 suggests that the process variation and mean may not be stable, with mean range 11.43 mg/dL and standard deviation within equal to 10.129 mg/dL. Point 41 in I chart and point 42 in MR chart failed test 1 for being outside the control limits. However, no special cause was determined to have influenced the variation.

The I-chart suggests the process may not be stable with mean 121.02 mg/dL and overall standard deviation of 11.736 mg/dL.

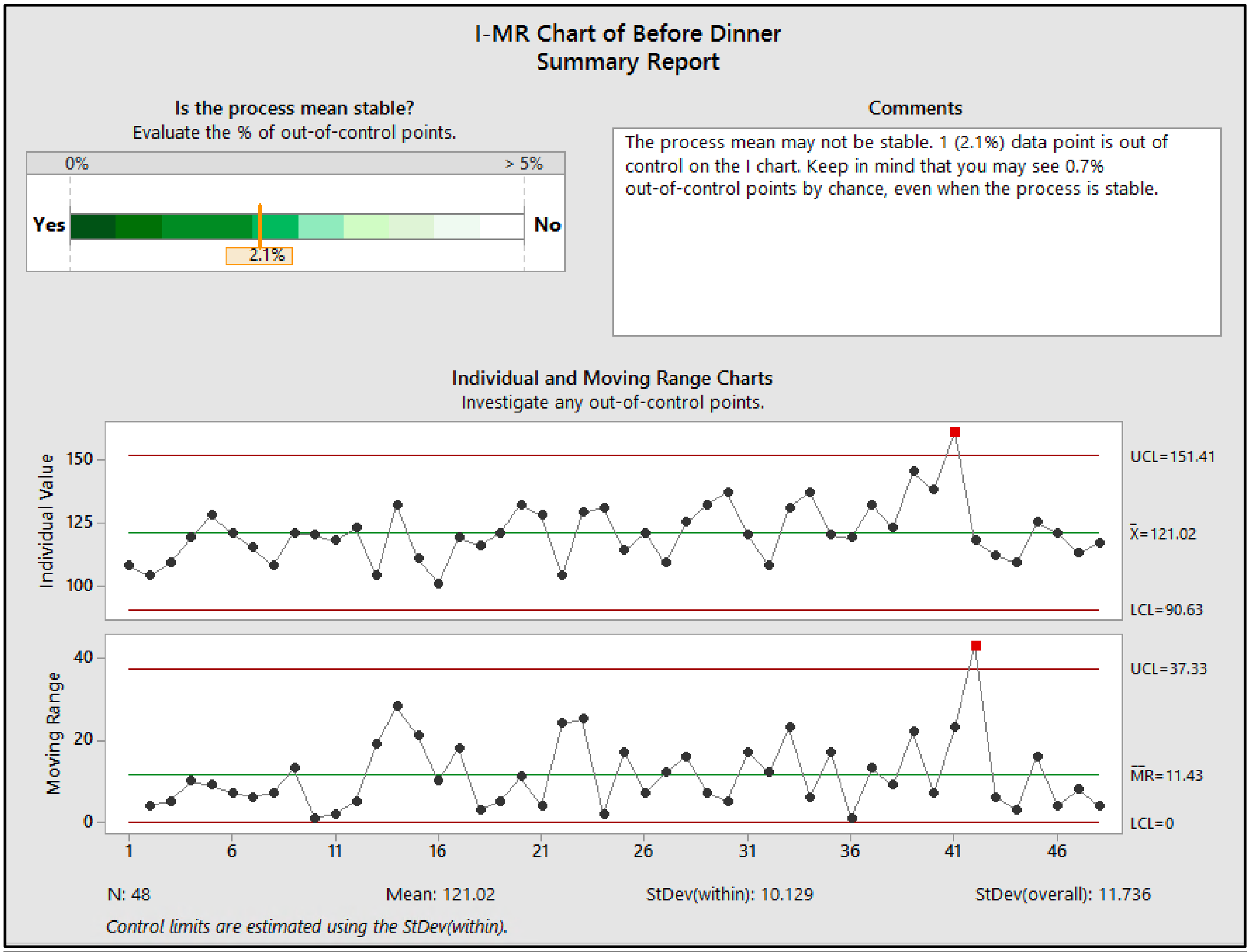

Figure 25: I-MR Chart of Blood Sugar Level Before Dinner

Figure 26 illustrates the I-MR chart with data point 41 and point 42 omitted from the data. The I-chart, with the omitted points, suggests the process variation and mean may not be stable. In the MR chart, the process mean range obtained was 10.57 mg/dL and standard deviation within equal to 9.3690 mg/dL. The process mean obtained was 120.22 mg/dL and overall standard deviation equal to 10.366 mg/dL.

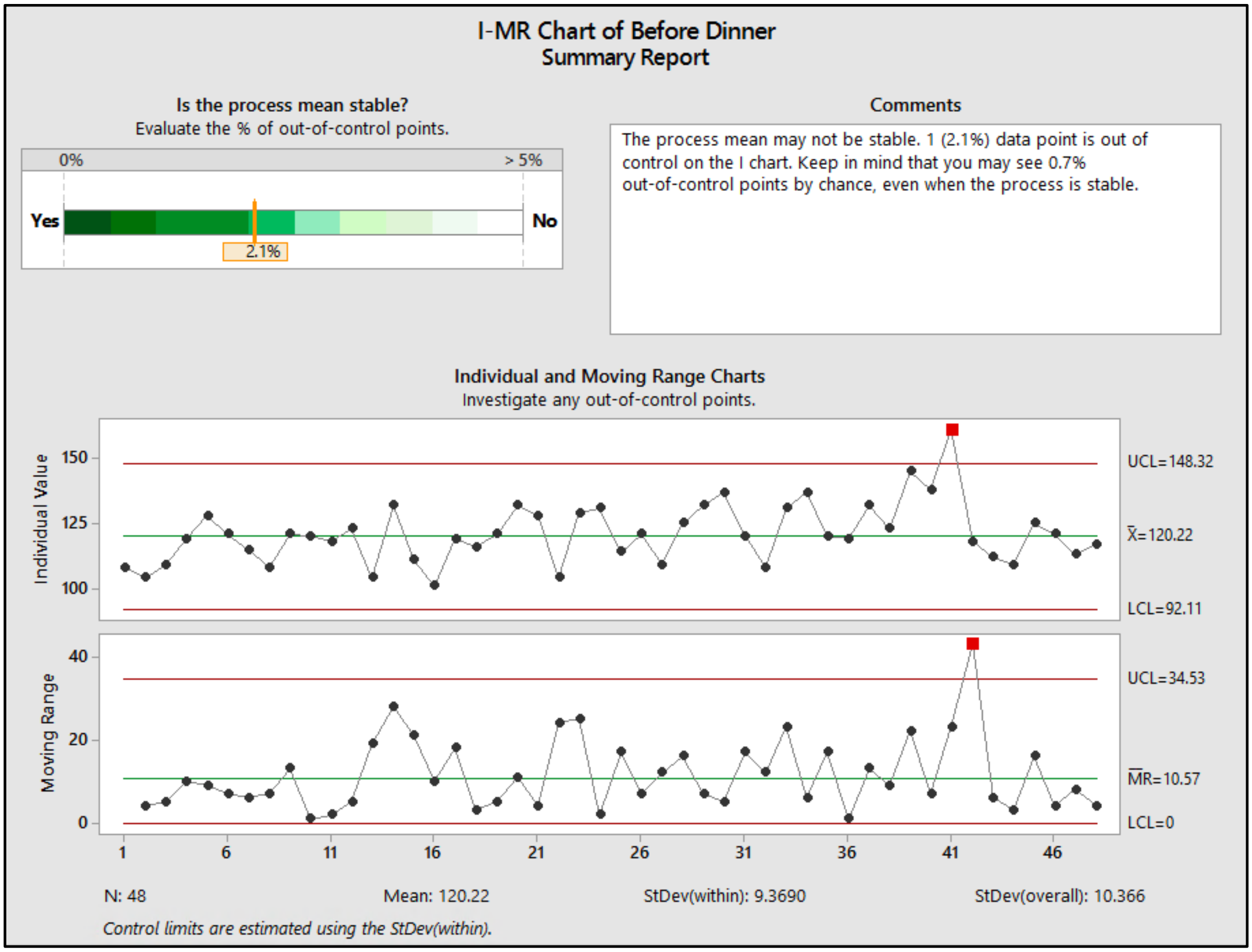

Figure 26: I-MR Chart of Blood Sugar Level Before Dinner with Data Points 41 and 42 Omitted

After Dinner

The MR chart in Figure 27 suggests that the process variation and mean may not be stable, with mean range 14.64 mg/dL and standard deviation within equal to 12.977 mg/dL. Point 41 in I chart and points 41 & 42 in MR chart failed test 1 for being outside the control limits. However, no special cause was determined to have influenced the variation.

The I-chart suggests the process may not be stable with mean 122.7 mg/dL and overall standard deviation of 14.455 mg/dL.

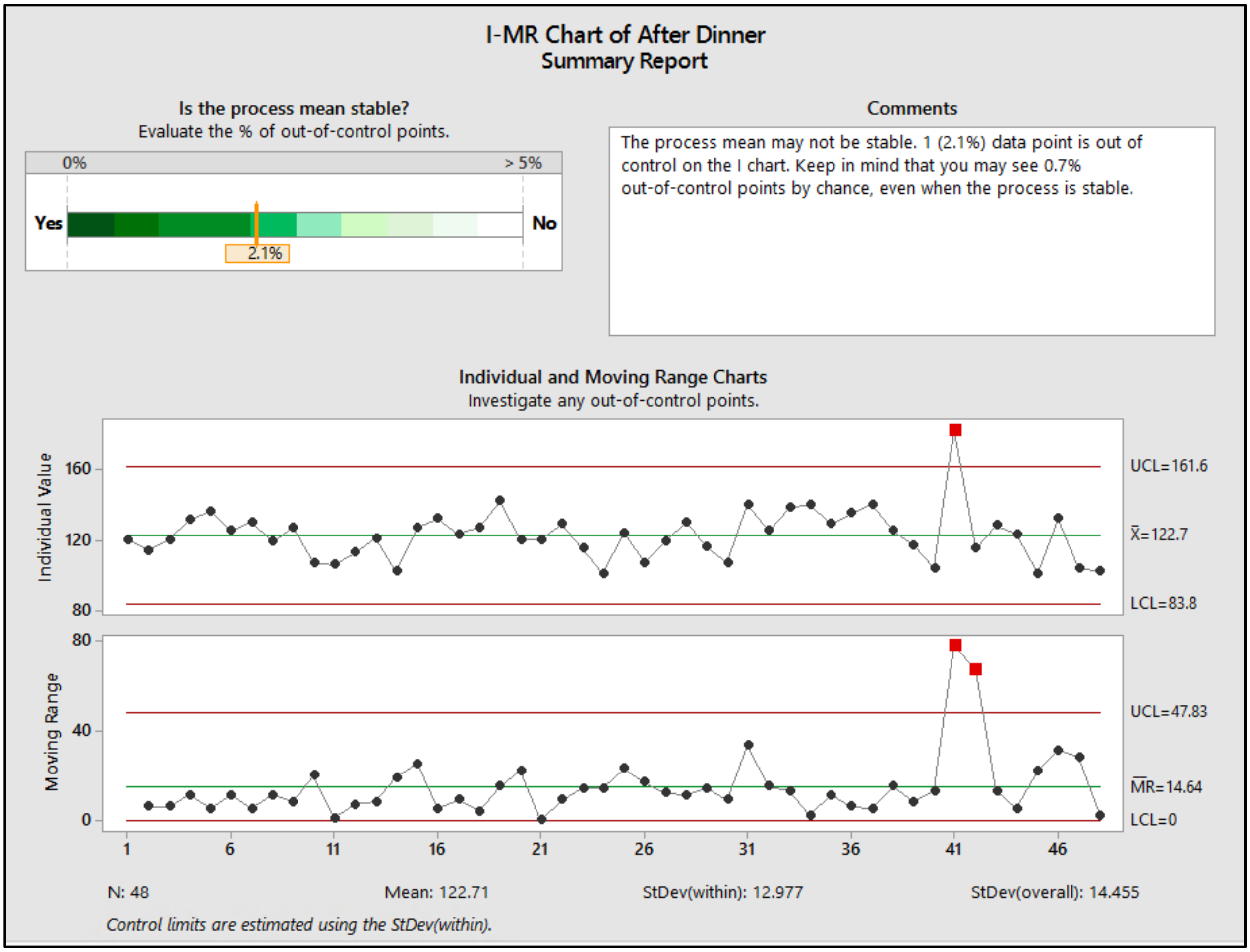

Figure 27: I-MR Chart of Blood Sugar Level After Dinner

Figure 28 illustrates the I-MR chart with data point 41 and point 42 omitted from the data. The I-chart, with the omitted points, suggests the process variation and mean may not be stable. In the MR chart, the process mean range obtained was 12.05 mg/dL and standard deviation within equal to 10.679 mg/dL. The process mean obtained was 121.6 mg/dL and overall standard deviation equal to 11.726 mg/dL.

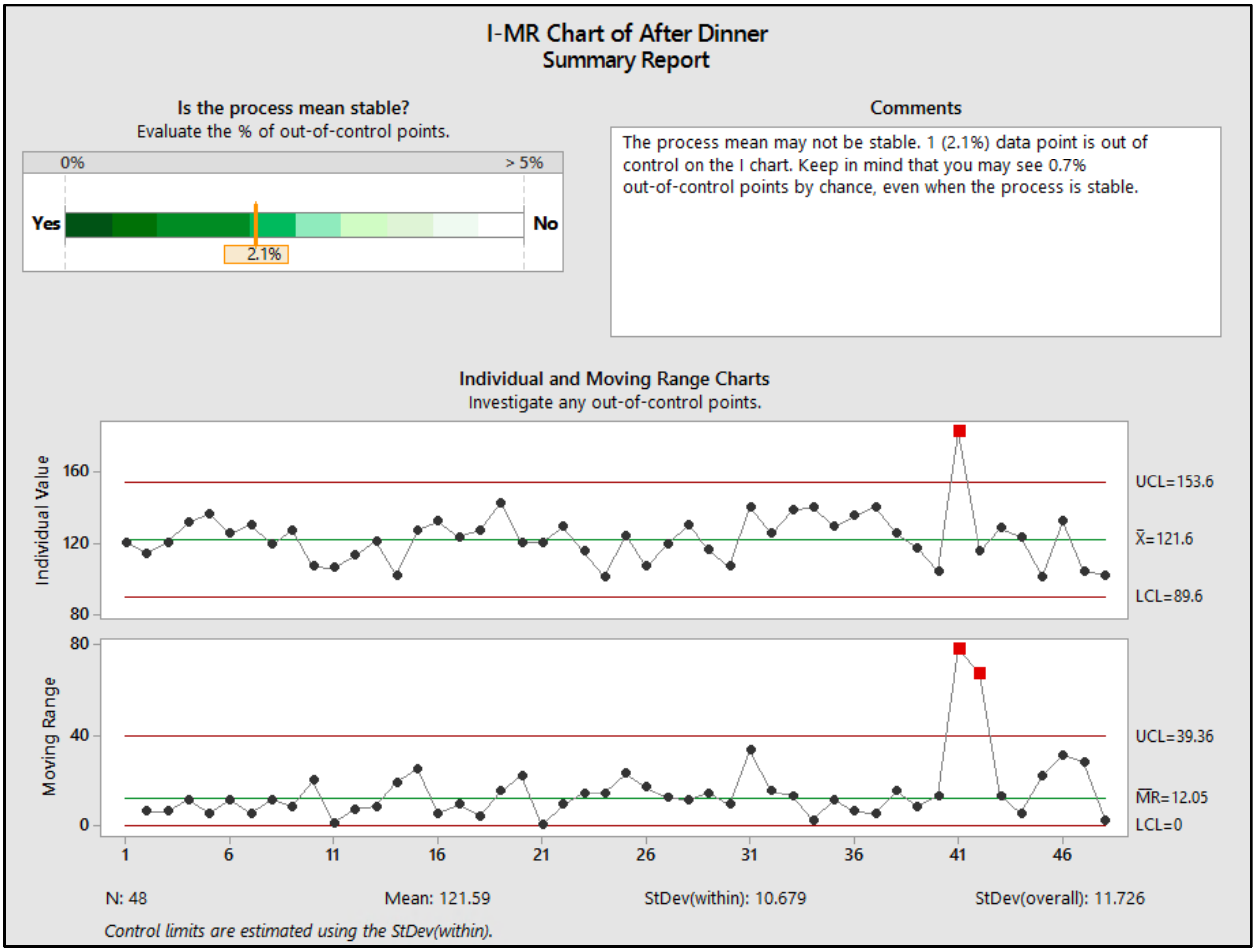

Figure 28: I-MR Chart of Blood Sugar Level After Dinner with Data Points 41 and 42 Omitted

Bedtime

The I-MR chart for observations at bedtime are illustrated in Figure 29. The MR chart suggests the variation in observations are stable, with a mean range of 11.15 mg/dL and standard deviation within equal to 9.8838 mg/dL. The I-chart suggests the mean is stable with mean 122.58 mg/dL and overall standard deviation of 10.467 mg/dL. So, the process mean and variation are stable as no points are out of control limits.

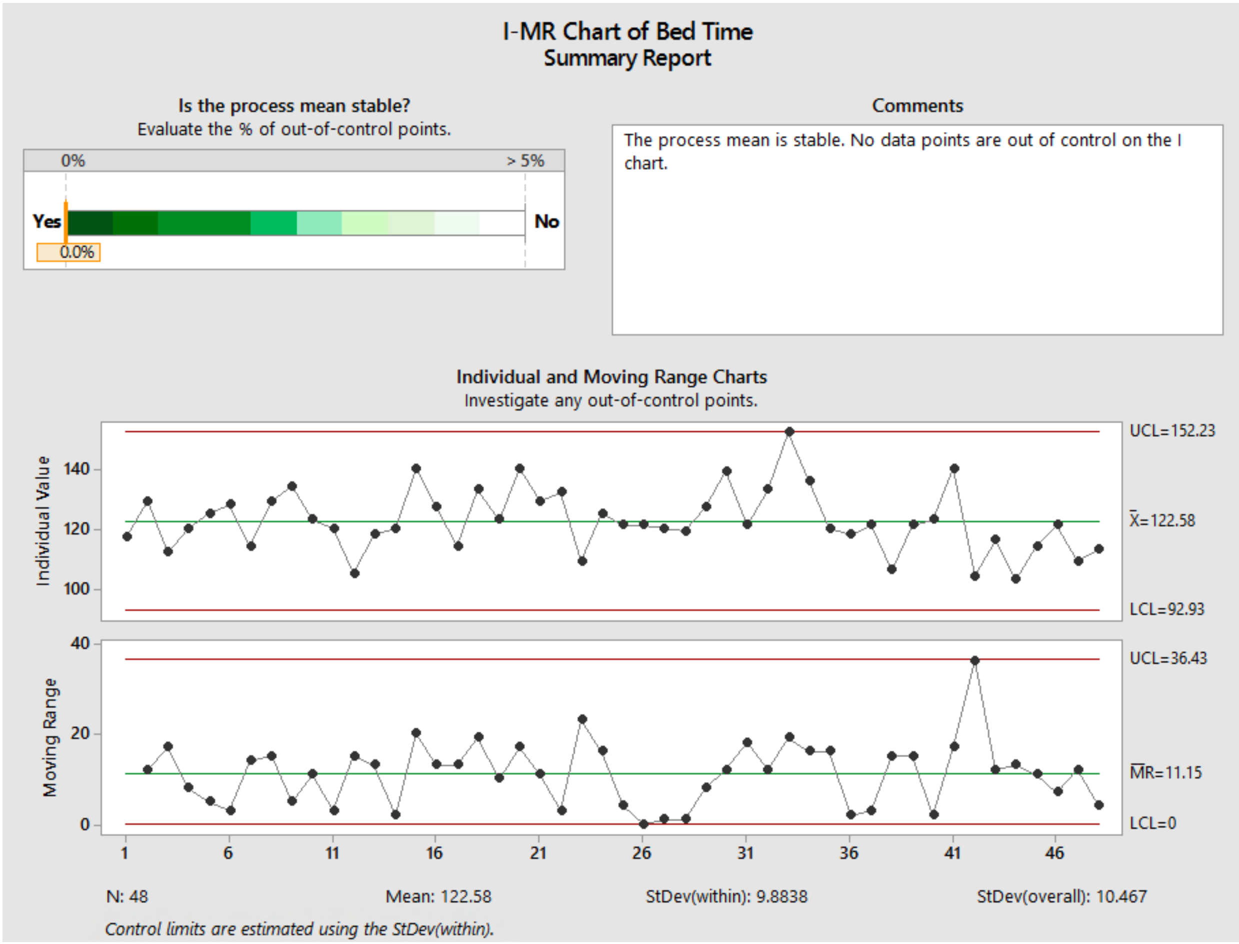

Figure 29: I-MR Chart of Blood Sugar Level at BedTime

Brainstorm/Fishbone Diagram/ 5 Whys

Through a collaboration effort, brainstorming was a tool used to list possible causes that can lead to problems and variation with the process. The cause-and-effect diagram in Figure 30 outlines possible causes that fall into 6 different categories; personal, measuring tools, diet, environment, lifestyle, and measuring process.

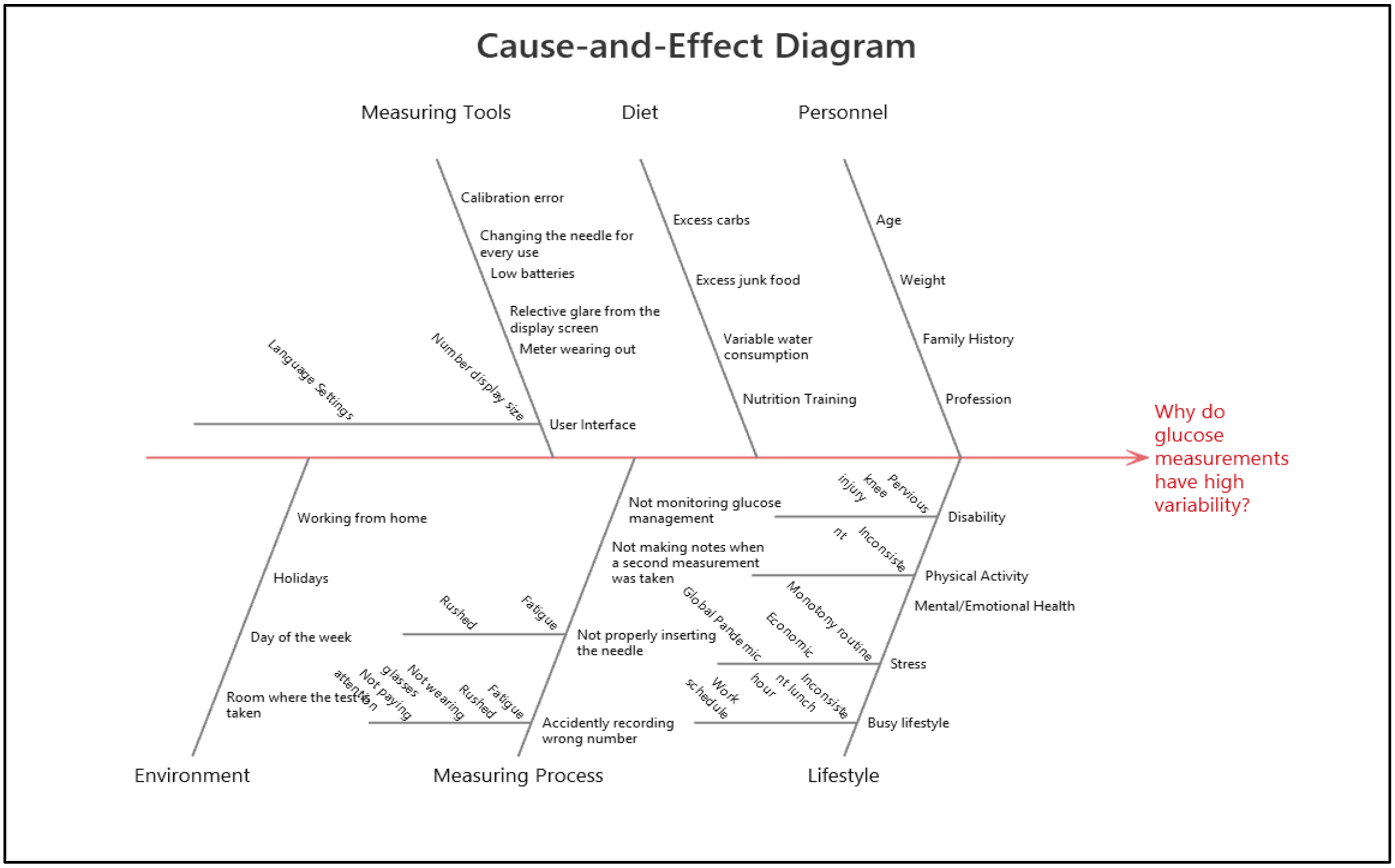

Figure 30: Cause-and Effect Diagram for Why do glucose measurements have high variability?

In creating the cause and effect diagram the 5-Why tool was utilized to help derive ideas for possible causes. An example of a 5-Why analysis based on one of the factors in the cause-and-effect diagram is:

1. **Why** do glucose measurements recorded by Bob have high variability?

   Because Bob is not making the measurement process correctly.
2. **Why** is Bob not making the measurement process correctly?

   Because Bob rushed through, was tired, had issues in visibility or maybe he didn’t insert the needle correctly
3. **Why** did Bob rush through, was tired, had issues in visibility when he measured his glucose-levels?

   Because he had a stressful day or had to do a lot of activities.
4. **Why** did Bob have a stressful day or had to do a lot of activities?

   Because Bob doesn't have a standardized glucose level measurement process, in other words he has an unorganized scheduled process.
5. **Why** hasn't Bob made a standardized process?

Because Bob is not familiar with the quality improvement process tools and analysis, so he is not able to find possible measurement errors

Since it is a recurrent operation, it should have been analyzed in an adequate way.

The last reason can be derived from the following cause: “Since Bob only records the data and does not inspect it or analyze it previously, his results have high variability.”

Opportunity for improvement

The cause-and-effect diagram were useful tools to help brainstorm possible causes for the variation in glucose levels. However, a pareto chart would have been useful to identify the most significant problems to work out. However, recording for the grams of proteins/carbohydrate grams consumed, counts of physical activity, and stress level would have been helpful information to identify improvements.

From the cause-and-effect diagram, the greatest opportunity identified for Bob’s case is to improve his monitoring of his sugar levels. This would require him to hand write his sugar levels for each observation and compare his management to recent recordings. For example, if glucose levels 2 hours after lunch are higher than usual (above 144 mg/dl from Figure 12), then it would be in Bob’s best interest to consider this information when preparing dinner later that day. Since the data does not indicate if good physical activity, good nutrition, or good stress management is maintained, this is the greatest opportunity for improvement we can make with the data collected.

From the histograms that have been normally distributed we can observe that in Figure 10(After Breakfast) we can see the data is slightly left skewed indicating that there are a number of values less than the mode. The advisable range of the glucose level after food is usually less than 180 mg/dL and from that of before food lies in the range of 80-130 mg/dL. From this we observe that the glucose levels after food are usually more than that of the advisable range before food which is shown by the left skewness in the histogram. Whereas if we observe the Figure 11(Before Lunch), we can see that the data is slightly right skewed indicating that there are a number of values greater than that of the mode and most of the data lies between the advisable range. It is recommended that Bob should work on what he consumes before lunch (typically after breakfast) that is causing for a large number of his measured glucose level to be more than the modal region of 120-130 which was explained by the right skewness. Therefore it is recommended that Bob controls the type of food he eats in the time frame after breakfast and before lunch.

In addition, from the control charts it is observed a trend of sugar levels increasing after observation 26 for after breakfast, before lunch, after lunch, after dinner. Observation 26 corresponds to March 26, 2020. Given the current cirstance with the global pandemic, Bob began working at home beginning March 25th, 2020. Therefore, it can be inferred that working at home and “the lockdown” could have been potential factors for variable glucose levels. Therefore, it is recommended that Bob is aware how he needs to control his nutrition and improve his physical activity while working from home. Bob later reported feeling very dizzy on April 10th, 2020, and therefore decided to eat healthier. This helps explain the shift in mean for control charts after observation 41 (April 10th, 2020) indicating that something from April 10th influenced future recordings for sugar levels.

Another opportunity we can see is located in the process flow diagram, we have seen that Bob only inserts the needle and takes his glucose level every time, but he doesn't seem to inspect if the needle is well placed or if the equipment has been correctly calibrated. The number of times Bob starts his measurements process cannot be changed since it is important for the doctor to have these data points if he requests the measurement values when he goes to the Doctor, this means the number of times he measures his glucose level during the day cannot be changed.

The new process map will contain an additional symbol of inspection, meaning that Bob will make sure when he is taking his measurements that there are no errors or the measurement tool has been set up accordingly.

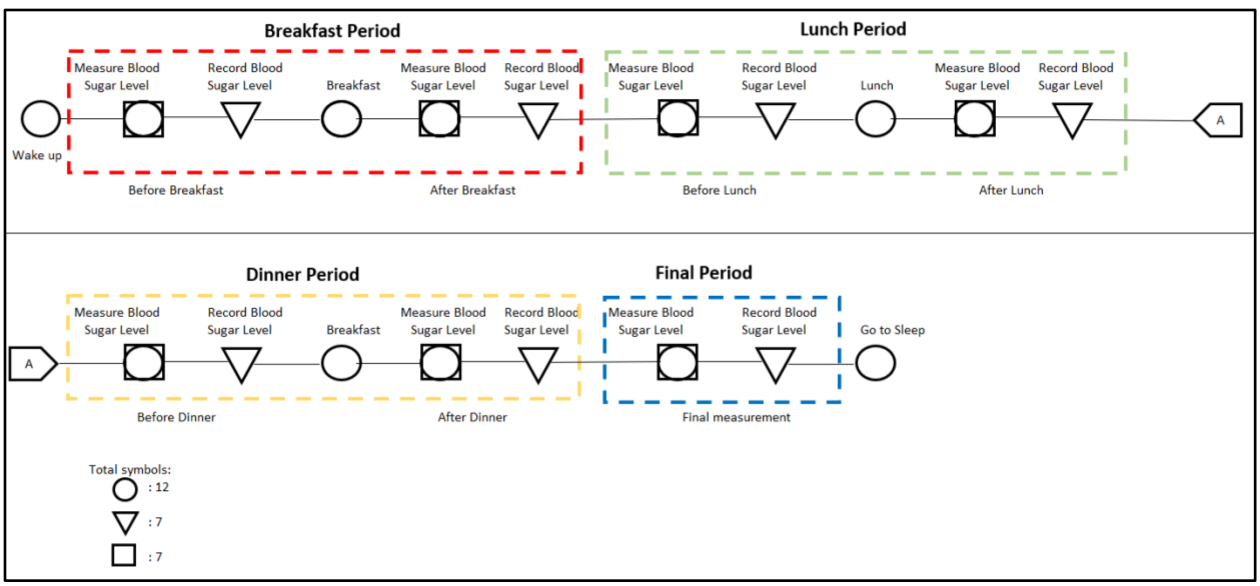

Figure 31: Improved process map

A practical way to implement the proposed improvement is through another quality tool named check sheet. The check sheet can be useful to further record and count the types of error that would arise during the glucose-level measurement, also it would help us verify the steps or times needed to ensure the correct processes of measurement. Based on the cause-effect diagram we have identified the possible errors in the measurement process and in the measurement tool. (as an option we can also add another types of errors from the other factors as well)

The proposed check sheet can be applied by Bob each time he measures his glucose-levels:

Process measurement verification check sheet

Date: ________
Time: ________

Initial checkpoint		
Did you or are you planning to have a lot of activities during the day?	Yes ☐	No ☐
Are you feeling tired?	Yes ☐	No ☐
Are you feeling with any disconfort or aches?	Yes ☐	No ☐
Did you had any injuries lately?	Yes ☐	No ☐

If you are taking measurements before a meal, please complete the next points:

Have you make any demanding physical activity Yes ☐ No ☐

If you are taking measurements after the meal, please complete the next points:

Have you eaten any high calories food?	Yes ☐	No ☐
Have you eaten any high carbohydrate food?	Yes ☐	No ☐
Have you eaten any food with high sugar?	Yes ☐	No ☐
Have you drank a lot of water?	Yes ☐	No ☐

Measurement tool and process	(✓)
Correct calibration	☐
Needle correctly inserted	☐
Adequate battery level	☐
Meter not worn out	☐
Space to store measurements	☐

Put a check when you finish the verification step.

Figure 32: Check Sheet for implementation

To count the type of errors occurred during the measurement process, we can use the following check sheet:

Error count checksheet

Count the number of times any of the following errors occur during the measurement process: (Insert dates) from : ____ to : ____

Needle not properly inserted	
Low battery (tool turns off during measuring)	
Cannot see value due to the reflective glare	
Missing a recorded number	
Failed to take notes of consecutive values	
Cannot visualize value due to error in monitor	
fall asleep while taking measurement	
Cannot visualize value (no eyeglasses)	
Other (specify) :	
Other (specify) :	
Other (specify) :	

Figure 33: Check Sheet for Error Count

With the check sheet, Bob should be able to have a better control over the measurement process and also be able to determine which error could be the most frequent one.