Implementation of Statistical Process Control in a High Volume Machining Center: Importance of Control Charts

by

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Bachelor of Science in Mechanical Engineering
University of Michigan in Ann Arbor, 2014

Submitted to the Department of Mechanical Engineering
In partial fulfillment of the requirements for the degree of

MASTER OF ENGINEERING IN MANUFACTURING
at the
MASSACHUSETTS INSTITUTE OF TECHNOLOGY

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Abstract

This thesis focuses on application of statistical process control (SPC) and control charts in a high volume machining center at Waters Corporation. The company has a need of a real time inspection and control methodology so that new hires as well as experienced operators can produce machined parts with high quality and low scrap rates. This thesis project was conducted by Zhu, Zhang and Udayshankar as a team, developing and applying multiple components of SPC at Waters. Zhang's thesis focuses on Gage Repeatability & Reproducibility and Udayshankar's thesis focuses on standard operating procedures (SOPs).

An SPC methodology flow chart is designed specifically for the company based on theoretical review of SPC methods and baseline data collection. Initially, the column machining process was out of control due to existing assignable causes such as tool breakage and tool wear. After an SOP is designed and operators trained to follow the SOP, the process was brought back into statistical control. A sampling plan is determined and individual control charts are used to achieve real time inspection in the long term.

As a result, scrap rate was reduced from 8% to 4% and potential savings in the column area is higher than $200,000. The SPC methodology will be scaled up to the entire machining center in the near future, which will have a potential annual savings of $600,000.

At the end of this thesis project, recommendations are made to Waters Corporation to help it maintain its status as a world class manufacturer. Major recommendations are to implement a database system for quality control, root cause analysis, training program and continuous process improvements.

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Duane Boning, Professor of Electrical Engineering and Computer Science

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Acknowledgements

Thank you to my advisors, Professor David Hardt and Professor Duane Boning for teaching us how to handle tough technical questions and how to immerse SPC into the company culture.

Thank you to Gabriel Kelly and Gregory Puszko for their continuous guidance at Waters Corporation during the project and the opportunity offered us to demonstrate our work in front of the global operations upper management team.

Special thanks to Leo Bates, Kerwin Cross, Mike Selent, Paul Pavone and Paul Lussier for their great support and guidance over the project.

Thank you to my team mates, Siddharth Udayshankar and Shaozheng Zhang, for our collaboration to produce such a great project result.

Thank you to Jim McPherson for creating such a great collaboration program between Waters Corporation and MIT, which was enabled me to apply lecture knowledge into practical engineering world.

Thank you to Jose Pacheco for managing such a great program, the Master of Engineering in Manufacturing.

Lastly, thank you to my family for their love and support during this challenging and exciting year at MIT.

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1 Introduction

The purpose of this thesis is to demonstrate how statistical process control (SPC) methodology can be implemented in high volume machining centers to reduce production scrap rate and improve manufacturing quality. Specifically, this thesis focuses on the application of control charts, a key element in SPC methodology, to monitor the manufacturing process, eliminate assignable variation and reduce natural variation. As a result, continuous improvement of the manufacturing processes can be achieved.

The thesis is based on an industrial project at Waters Corporation, an analytical instrument manufacturer in Milford, Massachusetts. The company primarily designs, manufactures, sells and services high performance liquid chromatography technology systems and support products, including chromatography columns, consumable products and comprehensive post-warranty service plans. The company machining center has grown rapidly with a rate higher than 10% each year since 2010. Specifically, more than 25% of the entire work force are new hires arriving in the past 18 months and over 40% are new hires joining the company in the past three years. As a result, direct scrap costs and associated quality losses have grown rapidly. Therefore, a real time inspection methodology and SPC is needed in the machining center to monitor the manufacturing activities and provide operators the opportunity to respond to production defects right after their appearance.

The scope of the thesis focuses on the column area, which makes up 40% of the company profits. The target is to prove that SPC methodology implementation can indeed reduce scrap rate and improve production quality. A portable documentation of the SPC methodology is generated to enable the manufacturing and quality engineers to apply and scale it up to the entire machining center, which indicates a potential annual savings of over 1.2 million dollars for the company.

Specifically, this thesis will focus on application and importance of control chart as a key component of the SPC methodology, to monitor the manufacturing process in real time and achieve defect reduction as a result. Initially, the process was found often to be out of control due to mean shifts. Two major problems were found that lead to the process going out of control: non-standardized tooling change timing and non-standardized tooling offset. As a result, standard operating procedures (SOPs) have been generated and training of operators were conducted to ensure standard operation across operators. As a result, the process was brought back into control and the scrap rate was largely reduced.

Section 2 will discuss background information about Waters Corporation in detail including a description of their machining center and column area. Introduction and historical review of SPC will also be included in this section to provide a brief overview of what SPC is and how it helps to improve production quality. Section 3 introduces a theoretical review of control charts as a quality control real time inspection methodology. Section 4 will focus on the actual application of control charts on the column area in Waters' machining center. The process being out of control is concluded, problems were addressed and thus reaction plans were generated. The functionality of reaction plans are proved by a second round of baseline data collection and the process is thereby brought back in control. Section 5 will illustrate the results of control chart implementation, including the possibility of real time inspection, defect rate reduction and potential savings in column area. Finally, in Section 6, future work and recommendations for Waters Corporation will be discussed to help it remain a world class manufacturer.

2 Background Information

In this chapter, background information on Waters Corporation, its machining center and column area as well as statistical process control will be covered. More importantly, the need for a real time inspection plan is identified due to extensive new hires joining in the machine center. Therefore, problem statement and control charts as a solution to the problem are also discusssed in this section.

This chapter was written in conjunction with project mates Shaozheng Zhang [1] and Siddharth Udayshankar [2], and thus a great portion of this chapter's content is similar among these three industrial theses.

2.1 Waters Corporation Overview

Waters Corporation, based in Milford, Massachusetts, is an analytical instrument manufacturer that primarily designs, manufactures, sells and services high performance liquid chromatography technology systems. Support products are also a big portion of Water's business including chromatography columns, consumable products and comprehensive post-warranty service plans.

The company's products are used by pharmaceutical, life science, biochemical, industrial, nutritional safety, environmental, academic and governmental customers working in research and development, quality assurance and other laboratory applications. There are two operating segments, Waters Division and TA Division, that have similar economic characteristics, product processes, products, and services. Because of these similarities, the two operating segments have been aggregated into one reporting segment for financial statement purposes.

2.2 The Waters Global Machining Center

The Waters Global Machining Center is around 50,000 sq. ft. located in Milford, Massachusetts, including a 29,000 sq. ft. Advanced Instrument Assembly & Accessory Kitting Operation facility and an 8,500 sq. ft. Clean Room for Optics, Critical Components and Micro Valves. The machining center produces over 2.7 million parts and 28,000 SKUs annually with 98% on-time delivery. More than 165 employees work in the machine shop including supervisors, engineers and operators. There are over 70 machines in the entire machining center including CNCs, wire EDM, precision lapping machine, metrology equipment, fused deposition modeling and laser welding.

The Machining Center runs 24 hours per day, 6 days a week and 52 weeks per year. There are two shifts per day, one ranging from 7:30am to 7:30pm and the other ranging from 7:30pm to 7:30am the following day. The machining center is divided up into four major departments: Column Area, Valve Area, NC Turning Area and NC Milling Area, as shown in the facility layout graph in Figure 1 [3].

Figure 1: Waters global machining center layout. 1 = Column Area, 2 = Valve Area, 3 = NC Turning Area and 4 = NC Milling Area [3].

2.3 Column Area

The scope of the thesis project focuses on the column area because around 40% of the company profit comes from the sales of columns. Therefore, SPC and control chart methods are firstly implemented in the column area, and can be scaled up to the entire machining center in the future. In this sub-section, column features, manufacturing processes, tooling and common production defects will be introduced.

2.3.1 Column Families

In the finished Waters instrument systems, the column is the area where liquid chromatography takes place. A common column has a symmetric geometry on the top and bottom. There are generally two parallel ranch flats on both ends. Extra fine threads are located between the flats and the ends as shown in Figure 2. Columns are categorized into families based on their outer diameters and length. Four major outer diameters, 1/4", 3/8", 1/2" and 1", are suitable for different chromatography applications. Every individual type of column is assigned with a unique part number that is recorded in the company SAP database system.

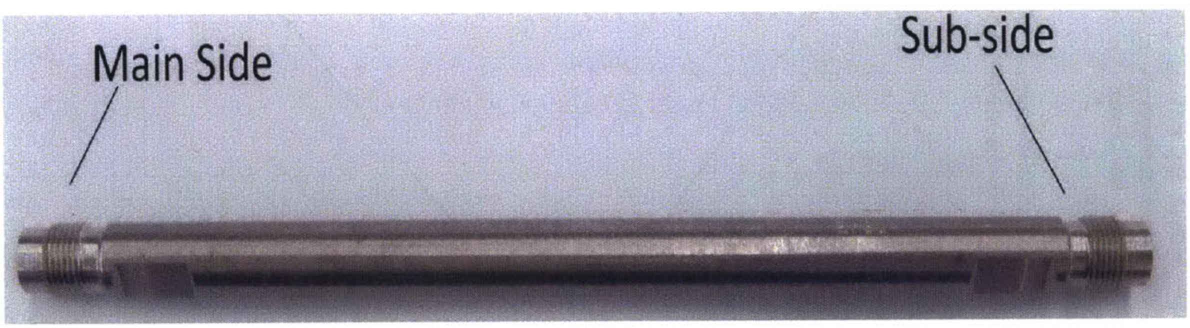


Figure 2: Sample column of quarter inch outer diameter family.

2.3.2 Column Manufacturing Process

Under the high pressure application environment, the sealing between the column and the chromatography machine is critical. Two features ensure good sealing performance: precise threads that create enough force, and fine finish on the top and bottom of the column that ensures excellent connection.

As introduced in Section 2.3.1, the column is usually symmetric on both ends. There are five major steps in the manufacturing process: turning outer surface profile, threading, engraving lot number, end milling ranch flats and cutting off. The major steps result in the geometry shown in Figure 3.

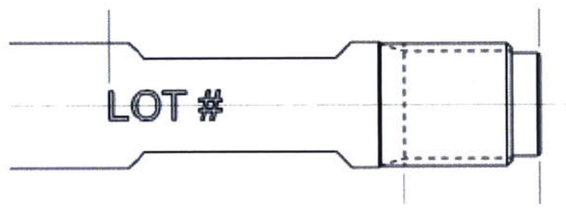


Figure 3: Sample column drawing to illustrate five major steps of its manufacturing process.

2.3.3 Major Tools

There are five tools used in the manufacturing process: single point turning carbide insert, threading insert, engraving tool, end mill and cut off insert. Three of them are shown in Figure 4. Among these tools, threading insert breaks more frequently because it has complex tip geometry and it works under higher load than other inserts.

Figure 4: From left to right: turning insert, threading insert and cut off insert.

2.3.4 Production Defects

After data collection and analysis based on characteristic sheets, production defect failure modes are identified from the highest frequency to the lowest, as shown in Figure 5. Notice that tool change itself contributes one quarter of the total defects, which means it is the major failure mode that SPC needs to tackle in order to successfully reduce production scrap rate. Threads, setup, tool wear and surface finish are also major failure modes that each contribute more than 10% of total production defects.

As a result, control charts are needed that provide the operator with value information about these failure modes in the form of signaling when the process is going out of control as it happens. Details will be discussed in the Section 3.3.

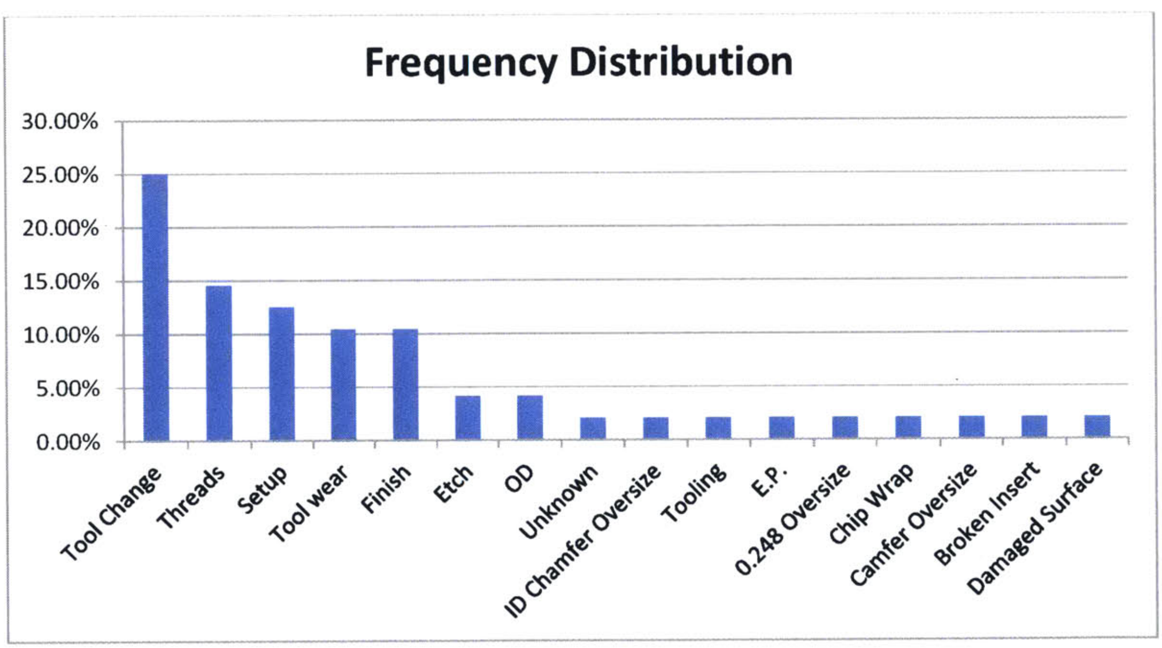


Figure 5: Production defects failure mode frequency distribution chart.

2.4 Introduction to Statistical Process Control (SPC)

If a product is to meet or exceed customer expectations, generally it should be produced by a process that is stable and repeatable. More precisely, the process must be capable of operating with little variability around the target or nominal dimensions of the product's quality characteristics. Statistical process control (SPC) is a powerful collection of problem-solving tools useful in achieving process stability and improving capability through the reduction of variability.

There are seven major tools of SPC: Histogram, Check Sheet, Pareto Chart, Cause-and-Effect Diagram, Defect Concentration Diagram, Scatter Diagram and Control Chart. Of the seven tools, the Shewhart control chart is the most technically sophisticated [3].

2.4.1 Origin of SPC

In 1924, Walter A. Shewhart of the Bell Telephone Laboratories developed the statistical control chart concept, which is often considered the formal beginning of statistical quality control. Toward the end of the 1920s, Harold F. Dodge and Harry G. Roming, both of Bell Telephone Laboratories, developed statistically based acceptance sampling as an alternative to 100% inspection. By the middle of the 1930s, statistical quality-control methods were in wide use at Western Electric, the manufacturing arm of the Bell System. Greatly influenced by Walter A. Shewhart, Williams E. Deming developed Deming's 14 points and seven deadly diseases of management, which is an important framework for implementing quality and productivity improvement [4].

2.4.2 Industrial Example of SPC Implementation

In this section, an example of the benefit of SPC implementation in a industrial setting is presented [5]. Leading edge technology and increasingly higher quality targets posed challenges to Texas Instruments' Printed Wiring Boards (PWB) group at Austin. Thanks to the training and involvement of all employees in statistical process control (SPC) real time inspection, their performance improved in quality, delivery and Work in Process (WIP) control.

In 1987, TI's management made a commitment to SPC from the top down. They appointed two full time quality control facilitators with responsibility for a serious program to train everybody in the company. Figure 6 represents the relative dollars of production scrap for plating defects, normalized to 1986=10, following SPC implementation. The benefits of SPC can be clearly seen from Figure 6. The quality loss due to production scrap was reduced to be 1/10 after the implementation of SPC. Apart from that, TI also successfully reduced lot size and setup time in key processing areas, achieving a total savings of $328,000 in just the first five months of 1987 [5].

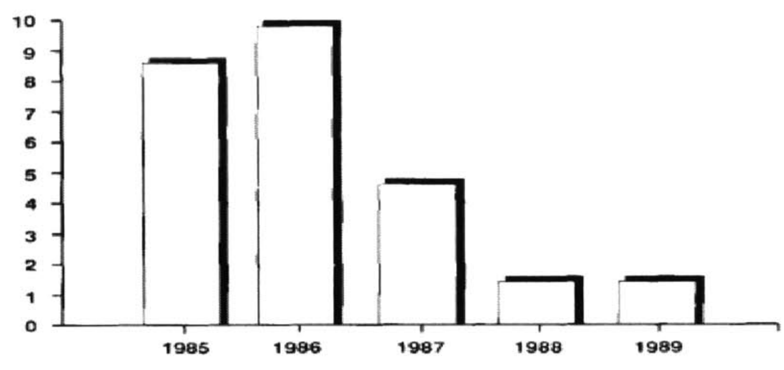


Figure 6: TI PWB plating scrap relative dollar scrap from 1985 to 1989 [5].

2.4.3 SPC Methodology Flow Chart

Figure 7 shows the designed SPC methodology flow chart. Key tools that our team implemented in the Waters project from this methodology are Gage Repeatability and Reproducibility, control chart, and process capability index Cpk.

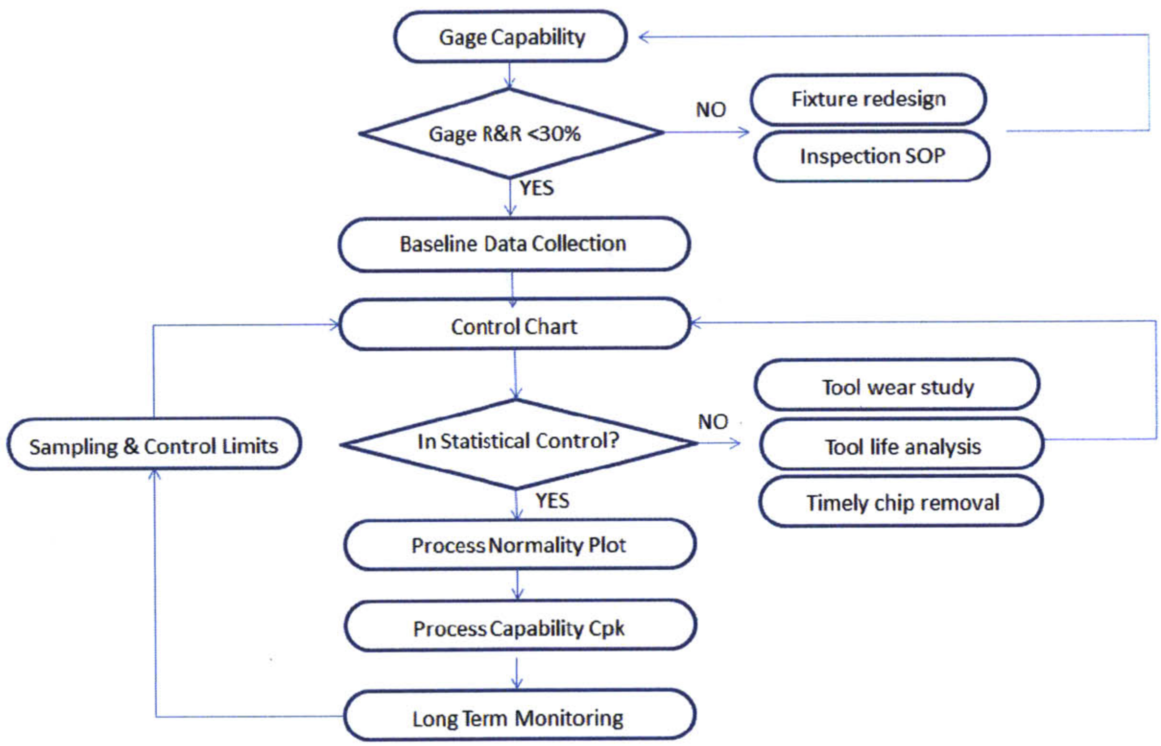


Figure 7: SPC implementation methodology flow chart.

When SPC is initially implemented in a new area, gage capability is always the first step. Gage R&R is the analysis tool to quantify gage capability, which is the gage variation over the total variation. When the ratio is less than 30%, then the gage is defined to be capable for measurement. When the gage is found to be non-capable, operators need to troubleshoot and solve problems related to the measurement system. For example, during our SPC implementation on Waters column area, a fixture was redesigned to reduce the gage variation, and an inspection SOP was documented to reduce the operator-to-operator variation.

After gage capability is confirmed, baseline data is collected in time sequence and thus a control chart is plotted to demonstrate whether the process is in statistical control or not according to the Western Electric Rules. From trouble shooting, tool wear, tool life and chip removal SOPs are documented and implemented as the reaction plans to bring the process back into control.

Process normality is then checked with 95% confidence from a normality plot, and process capability Cpk is calculated from Equation 2.1, where USL is the upper design specification, LSL is the lower design specification, μ is process mean and σ is process standard deviation.

$$Cpk = \min[\frac{USL - \mu}{3\sigma}, \frac{\mu - LSL}{3\sigma}] \tag{2.1}$$

The Cpk can also be easily understood by the definition of defects per million opportunities (DPMO), which means at certain Cpk value, there are corresponding numbers of defects per one million parts. Details are shown in Table 1.

Table 1. Cpk values and corresponding defect per million opportunities.

Cpk	0.33	0.67	1	1.33	1.67	2
DPMO	317,311	45,500	2,700	63	1	0.002

Per Waters company standard, a Cpk value above 1.33 is defined as a good process capability. The next phase is long term monitoring using control chart real time inspection. Sampling plan and control limits are determined according to the previous baseline data and capability of operators to follow the sampling procedure.

As a result, one cycle of SPC implementation is completed. Through long term monitoring of the control chart, the process will be continuously improved through flagging and reducing variation and thus improving process capability.

2.4.4 Value Added by SPC Implementation

By SPC implementation, Waters is able to use a data driven method to better control the quality of its product. For example, before SPC implementation, over 8% of scrap rate existed in the column area. After SPC is implemented, operators can troubleshoot the root cause of production defects, develop a corrective plan and thus prevent continuously producing defects right after a defect appears. As a result, a large amount of quality loss will be reduced due to the decrease of scrap rate.

More importantly, SPC methodology, especially the control chart, provides Waters machining center with a real time inspection tool that allows associated data collection and the subsequent improvement opportunities. As a result, engineers and operators have better control and documentation on how to properly use available resources to improve the production quality and yield performance.

Also, from the gage R&R study in the early stage of SPC implementation, the inspection accuracy and precision is largely improved. This means that the inspectors and engineers are more confident that the quality measurement data are trustworthy and valuable, which will enhance adoption and ongoing maintenance of the SPC system. In turn, the use of SPC will increase product quality, increase the customer satisfaction and thus improve the company's reputation.

In addition, during the SPC implementation process, an SOP of each stage is documented and implemented on the shop floor. Training sessions are also given to the operator section leads, which largely reduces the variation introduced by different operation between operators. In the long term, this will increase the process capability and help new hires to catch up with experienced employees.

Lastly, during the tool life and wear study to bring the process back into control, tools are better understood and utilized so that the overall cost of tools is largely reduced. Also, as the scrap rate is reduced, the corresponding productivity is increased.

2.5 Problem Statement

The Waters Machining Center is the largest supplier to Waters Corporation for machined and fabricated components. It supplies high complexity components to all of Waters' facilities and contract manufacturers worldwide. The Machining Center is an organization that has experienced a significant growth rate over the last few years, in excess of 10% per year since 2010. New hires over the last 18 months make up over 25% of the work force, with that number growing to 40% over the last three years. The Machining Center experiences a significant issue with machinist's ability to clearly understand real time inspection techniques and protocols, and to applying them to their everyday activities, in this ever increasing environment of production volume. As a result, the yield has dropped and the cost associated with diminished quality, both from direct scrap costs as well as associated productivity losses, has grown [6].

Waters believes that there is an opportunity to improve on its overall production inspection plan protocols, associated data collection and the subsequent improvement opportunities derived from such. Currently the machinists operate in a complex production environment, with excellent metrology resources. However, they have limited controls or documentation on how to properly use these resources to improve their quality and yield performance [6].

Therefore, this thesis focuses on the implementation of SPC in the Waters Machining Center that directs machinists towards a more standardized way of monitoring and controlling their processes. This control chart system in particular will center on control of critical dimensions while not forgoing other basic dimensions. After carefully evaluation, thread pitch diameter is identified to be the most critical dimension which will be the main focus in this thesis.

The whole project of SPC implementation was completed by a team of three, Haipei Zhu, Siddharth Udayshankar and Shaozheng Zhang. Each of us has his own focus and contribution in the entire project. The work by Udayshankar [2] focuses on standard operating procedure as to help new hires to follow a standardized way to implement the SPC system into the column area, and then expand to the entire Machining Center. The work by Zhang [1] focuses on gage capability study using Gage R&R method. By three rounds of gage R&R study, variations from inspection gages and from operators are largely reduced. As a result, gage capability is confirmed and trustworthy measurement data is guaranteed.

This thesis focuses on the benefits of applying control charts as a key component of the SPC methodology to reduce scrap rate and enable real time inspection. The column area is selected as our SPC implementation area. The main reason is that columns are the major company product earning more than 40% of all company net income in 2013. The target metric will be overall scrap rate reduction in percentage and the dollar value of quality loss reduction after control chart/SPC implementation in the column area.

2.6 Overall Approach

When the problem was presented to the team for the first time, it was evident that firstly, there needs to be a methodology set up to solve this issue and secondly, to ensure that the methodology is portable. The portability of the methodology was critical as the company wanted to implement statistical process control not only in the columns cell but also at the other manufacturing cells.

So, the team developed a methodology that was evaluated by implementing it in the columns cell, as summarized in Figure 8. Phase 1 of the project involved carrying out a Gage Repeatability and Reproducibility (Gage R&R) study to evaluate the measuring systems that were there in the columns cell. The next step was to collect baseline data. After collection of baseline data, the team analyzed the data and found trends that would help in creating sampling plans and also eliminating the variations. Phase 2 of the project involved developing sampling plans that made the life of the operator easier and also the inspection process faster. Assignable causes were eliminated by developing standard operating procedures that the operator was asked to follow. The final phase of the project was to develop control charts that would help the operator to stabilize the process and have it in a state of statistical control. The standard three sigma rules were incorporated to create the control charts. Also, reaction plans were incorporated in the standard operating procedures that would help the operator to bring the process back in control. A process capability study was carried out after the process was in statistical control to get an idea of the capability of the process to meet its specifications. The operators had to be trained in the concepts of statistical process control and the standard operating procedures that would help them in long-term monitoring of the process. By reducing the scrap rate and improving the quality of production, the team was successful in validating the adopted methodology.

A booklet was developed by the team and handed to Waters Corporation that contained standard operating procedures that could be used to implement statistical process control at a different manufacturing cell.

The entire work that we did as a team was broken into three parts. The Gage R&R study is covered by Shaozheng Zhang [1] and the development and value of standard operating procedures is discussed by Siddharth Udayshankar [2]. This thesis concentrates on the value added by application of control charts in a high volume machining center.

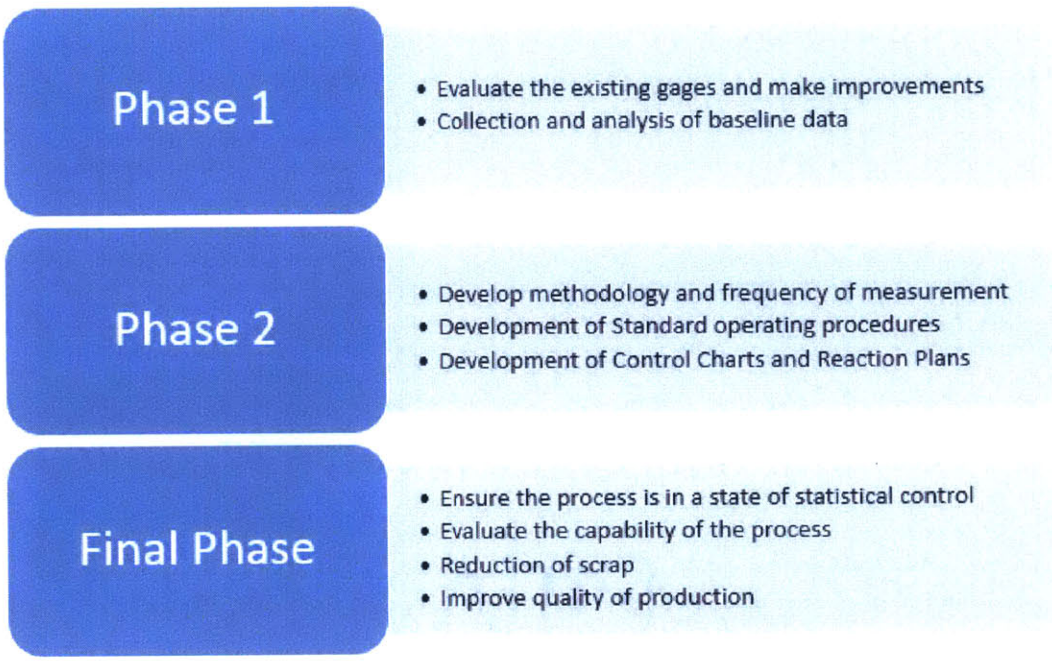


Figure 8: Three phases of SPC implementation project.

3 Theoretical Review of Control Charts

In this chapter, key components of control charts and their theoretical meaning will be introduced. Also, two states of process, in statistical control and out of control, will be demonstrated with examples. In addition, common reasons for the process to be out of control and methods to bring the process back into control will be covered. Lastly, after the process is stable and in process control, the methodology of applying control charts to monitor the process in the long term is also introduced. This section includes extensive citation from the book *Introduction to Statistical Quality Control* (Montgomery[4]).

3.1 Components of Control Charts

There are two common types of control charts: $\bar{x} - R$ chart and $\bar{x} - s$ chart, where the $\bar{x}$ chart shows the process mean in real time, the R chart monitors process variation range, and the S chart monitors process standard deviation. For our application, Waters really cares about process variation in the form of offsets from the target and standard deviation, so an individual chart will be used in the entire thesis.

In general, there are two sources of variations in a machining process: assignable cause variation and common cause variation. Assignable cause variations are due to factors impacting the system that can be specifically identified. Typical assignable variations include those from a tool break, tool wear, chip accumulation, temperature change, coolant adjustment etc. On the other hand, common cause variation is inherent variation from the system that remains after all identifiable variation sources have been eliminated. It is usually a random variable that follows a normal distribution. The $\bar{x}$ chart is used to monitor the process mean and help to detect system assignable causes. For example, if there is a tool break in the production process, a sudden jump of data will be captured in the $\bar{x}$ chart. The S chart is used to monitor the process common cause variation, and helps to detect assignable causes that change variance in the system. It can provide the user of the control charts information on how tight the process is from time to time.

There are two major components of the $\bar{x}$-s chart, the data points and control limits. In the following two subsections, theoretical meanings of these two components will be introduced in detail.

3.1.1 Data Points and Center Line

In practice, we usually will not know the process true mean μ and the true standard deviation σ. Therefore, they must be estimated from preliminary samples or subgroups taken when the process is thought to be in control. These estimates should usually be based on at least 20 to 25 samples. Suppose that *m* samples are available, each containing *n* observations on the quality characteristics. Typically, *n* will be small, often 4, 5 or 6. These small sample sizes usually result from the construction of rational subgroups and from the fact that the sampling and inspection costs associated with variables measurements are usually large [4]. In the $\bar{x}$ chart, $\bar{x}$ stands for a sample mean. Grand mean, which is shown as the center line in the $\bar{x}$ chart, is calculated as the average of sample means to best estimate the process true mean μ.

$$\bar{\bar{x}} = \frac{\overline{x_1} + \overline{x_2} + \cdots + \overline{x_m}}{m} \tag{3.1}$$

Figure 9 shows an example of an $\bar{x}$ chart with data points and center line labeled. In this example, the subgroup size is 5. Since there are 100 data points in total, the number of samples is 20. Subgroup mean is calculated and plotted in the chart and it is changing over time. Clearly from the chart, process group mean is around 110 to best estimate the process true mean shown as the center line.

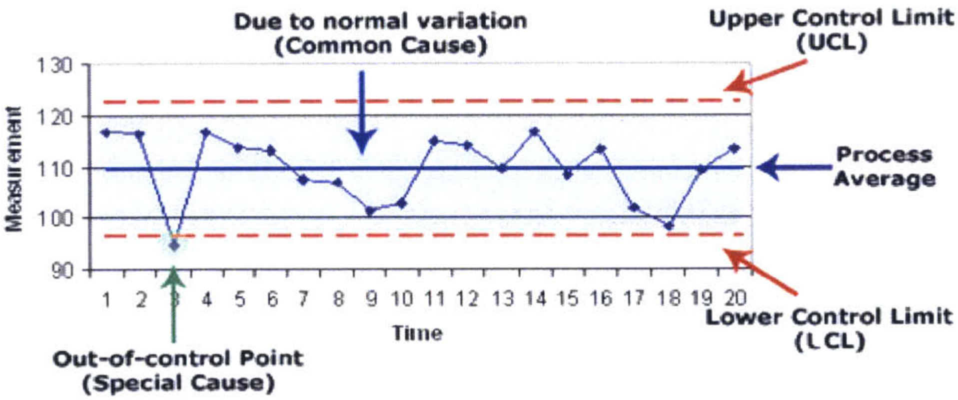


Figure 9: Example of control chart to illustrate data points, process average and control limits as its key components [6].

On the other hand, sample standard deviation S is usually used as an unbiased estimator of process true standard deviation σ. It is defined as

$$s = \sqrt{\frac{\sum_{i=1}^{n}(xi - \bar{x})^2}{n-1}} \tag{3.2}$$

Similar to $\bar{x}$ chart, the S chart is plotted with the corresponding subgroup of size n. Each data point on the chart is the standard deviation within the subgroup. In the previous example, with a subgroup size of 5, each point is calculated by Equation 3.2 with n=5. There is also a center line in the S chart, which is the average value of each subgroup standard deviation S [4]. Therefore, it is defined as

$$s = \frac{s_1 + s_2 + \cdots + s_m}{m} \tag{3.3}$$

3.1.2 Control Limits

Control limits are driven by the natural variability of the process measured by the process standard deviation σ, which are the natural variation limits of the process. There is no connection or relationship between the control limits and specification limits on the $\bar{x}$ – s chart. It is customary to define the upper and lower control limit, UCL and LCL, as 3σ above and below the process mean. The specification limits, on the other hand, are determined externally. They may be set by management, the manufacturing engineers, the customer, or the product development engineers [4].

Theoretically, the process standard deviation is estimated by Equation 3.4. Then the $\bar{x}$ chart control limits are defined in Equation 3.5 and S chart control limits are defined in Equation 3.6, where c4 is a constant that depends on the sample size n, which can be found in the table of *Factors for Constructing Variables Control Charts* [7].

$$\sigma = \frac{\bar{s}}{c4} \tag{3.4}$$

$$\begin{cases} UCL = \bar{\bar{x}} + \dfrac{3}{c4\sqrt{n}}\,\bar{s} \\ LCL = \bar{\bar{x}} - \dfrac{3}{c4\sqrt{n}}\,\bar{s} \end{cases} \tag{3.5}$$

$$\begin{cases} UCL = (1 + \dfrac{3}{c4}\sqrt{1 - c4^2})\,\bar{s} \\ LCL = (1 - \dfrac{3}{c4}\sqrt{1 - c4^2})\,\bar{s} \end{cases} \tag{3.6}$$

In order to easily process data and control charts, the Minitab software package was used in this thesis. To simplify the control limit calculations, default control limit formulas were directly used. A pooled standard deviation method to estimate standard deviation, Equation 3.7, is used because it is accurate and the most commonly used method in the industry. Therefore, $\bar{x}$ chart control limits are defined in Equation 3.8 and s chart control limits are defined in Equation 3.9 [8]. Again, c4, c5 and d are unbiasing constants that can be found from *Understanding Statistical Process Control* by D. J. Wheeler and D. S. Chambers [7].

$$\begin{cases} \sigma \approx \dfrac{Sp}{c4(d+1)} \\ Sp = \sqrt{\dfrac{\sum_i \sum_j (xij - \bar{x}i)^2}{\sum_i (ni - 1)}} \end{cases} \tag{3.7}$$

$$\begin{cases} UCL = \bar{\bar{x}} + \dfrac{3}{\sqrt{n}}\,\sigma \\ LCL = \bar{\bar{x}} - \dfrac{3}{\sqrt{n}}\,\sigma \end{cases} \tag{3.8}$$

$$\begin{cases} UCL = (1 + 3\,\frac{c5}{c4})\sigma \\ LCL = \left(1 - 3\,\frac{c5}{c4}\right)\sigma \end{cases} \tag{3.9}$$

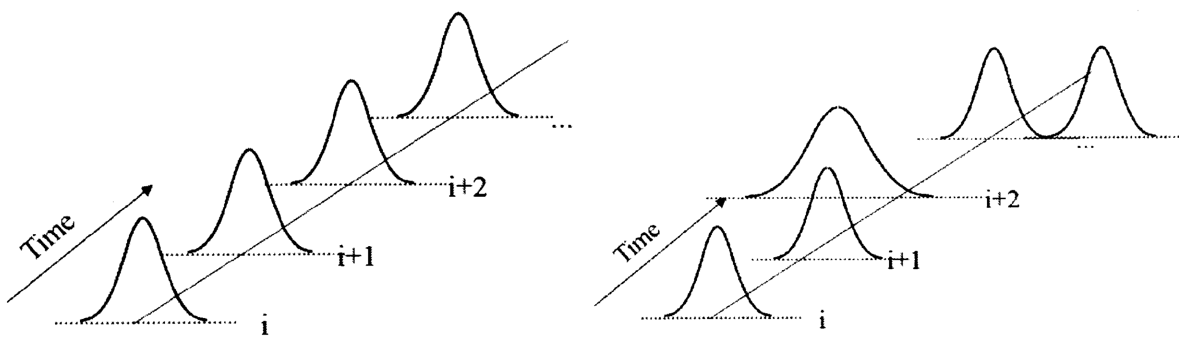
3.2 Process in Statistical Control

A process that is in statistical control is critical in the SPC implementation process because only when the process is in control, can the control limits, process capability analysis and long term monitoring be meaningful. Therefore, in this subsection, definition and rules to determine if the process is in control are introduced.

3.2.1 Definition of Process in Statistical Control

As mentioned in previous sections, there are two sources of variations in a process: assignable cause variation and common cause variation. In order to achieve the target of process improvement, assignable cause variation needs to be eliminated and common cause variation needs to be minimized. When assignable cause variation is eliminated, the process is said to be in statistical control. Therefore, a process being in statistical control is defined as a process with stationary behavior that only has common cause variation. Here stationary behavior means that the process data vary around a fixed mean in a stable or predictable manner [4].

An example of process in and out of control is shown in Figure 10 (a) and (b), respectively. When the process is in control, it maintains the same normal distribution behavior with close enough mean and standard deviation as time flows. If either process mean or standard deviation changes at a certain time spot, we would define the process as out of control at that time.



(a) (b)

Figure 10: Examples of process in statistical control (a) and process out of control (b) [9].

Therefore, there are two factors that can bring a process out of control: non-stationary behavior and data being out of certain limits. For the first factor, a mean shift in an $\bar{x}$ chart indicates that the process mean has changed, and a mean shift in an S chart means the process variation is non stationary. For the second factor, a point that is beyond the control limit (which is usually three sample standard deviations from the mean) flags that the process is likely to be out of control at that specific point.

3.2.2 Rules to Define Process Out of Control

The process being in statistical control is defined in the previous subsection. In order to quickly identify when the process is out of control in a standardized way, rules are defined to test for better unnatural pattern recognition. Shewhart defined Rule 1, which is one or more points more than three sigma from the mean [10]. Rule 1 is the most basic rule and is widely used by other rule definers. The Western Electric Rules added to the Shewhart criterion, and provides tests covering such unnatural patterns as smaller or sustained shifts, mixtures, stratification and systematic variation. To be able to apply these tests, the region between control limits in a control chart must be divided into six zones, each of one sigma width, and the location of the predefined sequences of the points in relation to these zones must be evaluated. As normal distribution of the applied sample statistics is supposed, the possibility of a point located in zone C (within ± 1 sigma zone) is expected to be 68.27%, in zone B (outside zone C but within ±2 sigma zone) is expected to be 27.18% and in zone A (outside zone B and C but within ±3 sigma zone) is expected to be 4.28% when the process is statistically stable [11].

The Western Electric Company Handbook [10] defined Rules 2, 3, 4, 6 and 8. Details can be seen from Table 2. Rules 2-4 were designed for quicker identification of the shifts from the mean as compared to Rule 1. All Rules from 1 to 4 are applicable to all $\bar{x}$ – R and $\bar{x}$ – s charts.

Apart from Rule 1 and the Western Electric Rules, there are other rules that have been defined in the industry based on its own applications. Table 2 illustrates the most common and widely used rules to identify when the process may be out of statistical control.

Table 2: Rules and their applications in industry [11].

	Shewhart Rule	Western Electric Rules	Nelson Tests	ISO 8258	AIAG Rules	Boeing ASQ Rules	Trietsch
Rule1 One or more points more than 3 sigma from the mean	✓	✓	✓	✓	✓	✓	✓
Rule 2 2 of 3 consecutive points between 2 and 3 sigma from the mean		✓	✓	✓		✓	✓
Rule 3 4 of 5 consecutive points between 1 and 3 sigma from the mean		✓	✓	✓		✓	✓
Rule 4 8 consecutive points on one side of the mean		✓	✓	✓	✓	✓	✓
Rule 5 6 consecutive points steadily increasing or decreasing			✓	✓	✓		✓
Rule 6 15 consecutive points both above and below central line	✓	✓	✓	✓			✓
Rule 7 14 consecutive points alternating up and down			✓	✓			✓
Rule 8 8 points in a row on both sides of the central line		✓	✓	✓			✓

3.3 Bringing a Process Back into Control

A process being in statistical control is critical as discussed in the previous section. After rules are applied to identify whether the process is in control or not, methods to bring the process back into control are needed. In this subsection, three steps to bringing a process back into control are introduced: trouble shooting, reaction plan and data collection to prove functionality of reaction plan.

3.3.1 Troubleshooting

When a sign of the process going out of control appears, troubleshooting is needed to determine the root cause of the assignable cause variation and thus help to bring the process back in control. There are three major methods of troubleshooting: event recording, cause and effect (fishbone) diagrams and Design of Experiments (DOE). The first two methods are more experience-based qualitative approaches and DOE is a more data based quantitative approach. The qualitative approaches are easy and fast to implement and the quantitative approach is more accurate and trustworthy.

Event recording is a preventive method instead of a corrective method. All events that have any possibility to cause process change are recorded in a notebook or database system. The main purpose of event recording is to uncover what has changed before and after the sign of the process out of control appears. Specifically in this thesis, events refer to tool break, tool change, tool wear, etc. Information of time, operator, action and reaction plan are also recorded with the events to help the analyst to link the events with collected data and control charts such that the root cause of the process can be easily determined.

Figure 11 is an example of how event recording is applied in our thesis project to help root cause analysis and event troubleshooting. In the figure, the comments column is critical because it helps the analyst to clearly understand details about what happened and what the operator did to solve the problem. Part number, time, measurement and actions are the major components of the record. This method is suitable to tackle obvious causes of a problem.

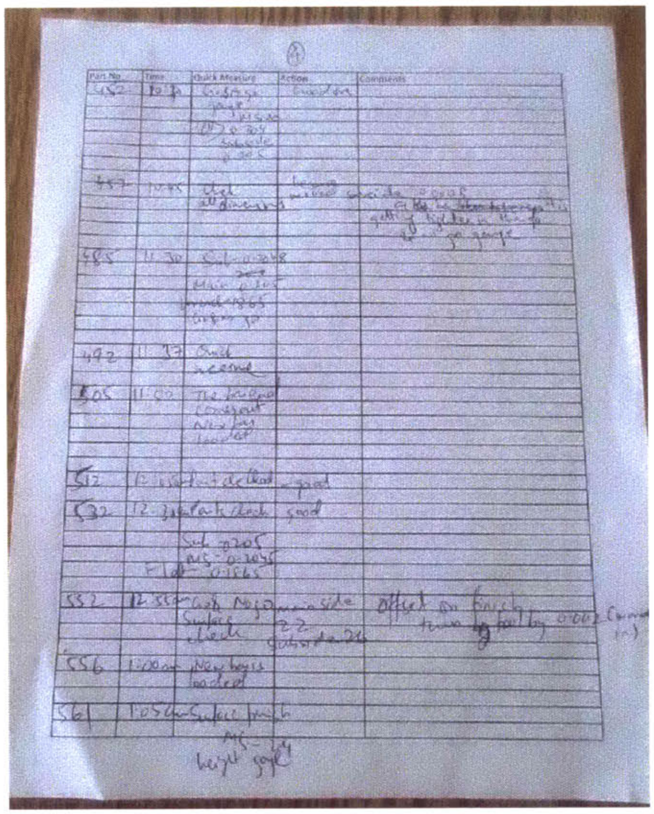


Figure 11: Example of event recording method to troubleshoot the root cause of process out of control.

Once a defect, error, or problem has been identified and isolated for further study, we must begin to analyze potential causes of this undesirable effect. In situations where causes are not obvious, the cause and effect (fishbone) diagram is a formal tool frequently useful in unlayering potential causes. The cause and effect diagram is very useful in the Analyze and Improve steps of the DMAIC (Define, Measure, Analyze, Improve and Control) methodology to continuously improve process in a data-driven improvement cycle. The steps in constructing the cause and effect diagram are shown below [4].

1. Define the problem or effect to be analyzed.
2. Form the team to perform the analysis. Often the team will uncover potential causes through brainstorming.
3. Draw the effect box and the center line.
4. Specify the major potential cause categories and join them as boxes connected to the center line.
5. Identify the possible causes and classify them into the categories in step 4. Create new categories, if necessary.
6. Rank order the causes to identify those that seem most likely to impact the problem.
7. Take corrective action.

One classical example of the cause and effect diagram is the analysis of a tank defect problem [4]. The team elected to lay out the major categories of tank defects as machines, materials, methods, personnel, measurement and the environment. A brainstorming session ensues to identify the various sub-causes in each of these major categories and to prepare the diagram in Figure 12. Then through discussion and the process of elimination, the group decides that materials and methods contained the most likely cause categories.

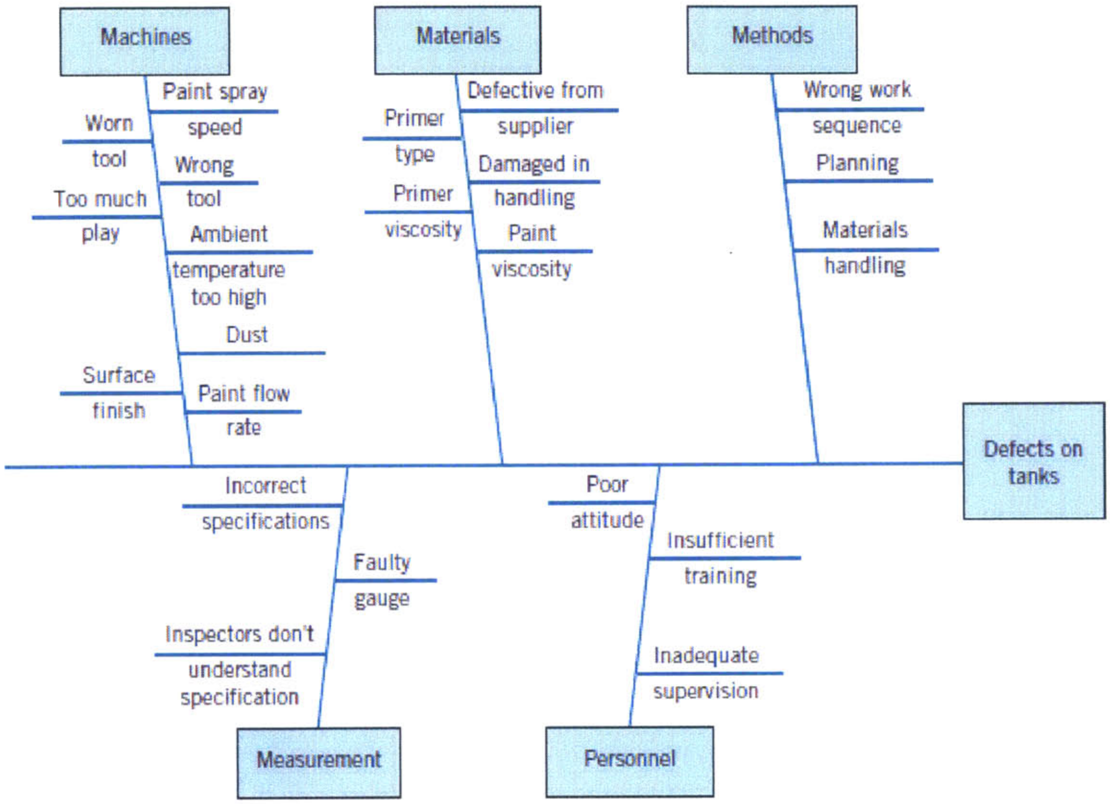


Figure 12: Example of cause and effect diagram to uncover root cause of defects on tanks [4].

Cause and effect analysis is an extremely powerful tool. A highly detailed cause and effect diagram can serve as an effective troubleshooting aid. Furthermore, the construction of a cause and effect diagram as a team experience tends to get people involved in attacking a problem rather than in affixing blame [4].

Lastly, Design of Experiments (DOE) is a powerful quantitative tool for problem troubleshooting. It also helps to identify magnitude and direction of important process variable effects, demonstrate interaction among process variables and optimize system performance. To use this approach, it is necessary that everyone involved in the experiment have a clear idea in advance of the objective of the experiment, exactly what factors are to be studied, how the experiment is to be conducted, and at least a qualitative understanding of how the data will be analyzed. According to Montgomery (2005) [4], an outline of the recommended procedure is shown below.

1. Recognition of and statement of the problem
2. Choice of factors and levels
3. Selection of the response variable
4. Choice of experimental design
5. Performing the experiment
6. Data analysis
7. Conclusions and recommendations.

3.3.2 Reaction Plan

Once the root cause of the problem is uncovered, a corresponding reaction plan is developed to solve the problem. The simplest example is when a tool breaks, tool change is its reaction plan. It is also called an out-of-control-action-plan (OCAP). The OCAP consists of *checkpoints*, which are potential assignable causes, and *terminators*, which are actions taken to resolve the out-of-control condition, preferably by eliminating the assignable cause. It is very important that the OCAP specify as complete a set as possible of checkpoints and terminators, and that these be arranged in an order that facilitates process diagnostic activities. An OCAP is a *living document* in the sense that it will be modified over time as more knowledge and understanding of the process is gained. Consequently, when a control chart is introduced, an initial OCAP should accompany it [4].

3.3.3 Data Collection to Prove Functionality of Reaction Plan

An important step following reaction plan is the data collection to prove its functionality. Baseline data is collected in production time consequence to plot run chart and control chart to demonstrate that the out-of-control process has been brought back into control because of the implementation of the reaction plan. As a result, the reaction is proved to be functional and can be documented into a standard operating procedure (SOP) and released into the corporate data system. Training of the SOP will thus be provided to all operators to ensure standardized operation in the entire machining center.

3.4 Sampling Plan and Long Term Monitoring

The sampling plan is concerned with inspection and decision-making regarding products, one of the oldest aspects of quality assurance. It is critical to determine a suitable sampling frequency – a tradeoff between providing enough information of the production quality and allocating sampling effort. Current industry practice tends to favor smaller, more frequent samples, particularly in high-volume manufacturing processes, or where a great many types of assignable causes can occur. As automatic sensing and measurement technology develops, it is becoming possible to greatly increase sampling frequencies. Ultimately, 100% inspection can be achieved. However, since automatic measurement system and microcomputers with SPC software are not commonly used in Waters Corporation, 100% inspection requires too much human effort so that a rational sampling frequency is needed to ensure high quality of production inspection and not too much extra work load that is added onto the operators [4].

A quantitative way to evaluate the decisions regarding sampling frequency is through the average run length (ARL) of the control chart as shown in Equation 3.12, where P is the probability that any point exceeds the control limits. Essentially, the ARL is the average number of points that must be plotted before a point indicates an out-of-control condition.

$$ARL = \frac{1}{p} \tag{3.12}$$

After sampling frequency is determined, control charts can be applied to long-term monitoring the machining process. Whenever there is a signal showing that the process has a likelihood of being out of control, the corresponding reaction plan is executed to eliminate the assignable cause and keep the process within statistical control.

As a result, one full cycle of SPC implementation completes. Through the application of control chart, common cause variation will be monitored in the S chart. The process can be continuously improved by ensuring that most assignable causes are eliminated. The resulting value of process capability index Cpk with assignable cause variation eliminated can be used to quantify the continuous improvement of the process. When Cpk reaches 2.00, it means the process reaches the Six Sigma standard.

4 System Improvement by Control Chart Implementation

In previous sections, control charts and statistical process control methodology are introduced and shown by theory to be powerful tools to improve production quality. This section focuses mainly on the application of control charts in the column area of the Waters' Global Machining Center. An example of thread pitch diameter will be used throughout this section because it has more assignable cause variation than other dimensions. Therefore, it is easier to use this single dimension to demonstrate how to eliminate assignable cause variations and bring the process back in control under Western Electric Rules [10].

In this section, initial baseline data is collected and control charts are plotted to analyze assignable cause variations. After realizing the benefit of the event record method to troubleshoot root causes for obvious assignable cause variations, a second round of baseline data is collected to visualize tool wear and tool break as two major assignable events on control charts. After that, reaction plans are designed separately to handle tool wear and tool break to bring the process back into control. Sampling frequency is determined according to feasibility in the machining center and data analysis. The ProLink software package is set up in the column area and used for long-term control chart monitoring.

4.1 Baseline Data Collection and Control Chart

In order to collect enough baseline data in time sequence, around 1500 parts in two production orders were produced and arranged in time sequence. There was no sampling plan adopted initially, which means every single part was measured. Critical dimensions for the inspection are pitch diameter of the thread, outer diameter and wrench flat thickness. Four other lower priority but still important dimensions were also monitored in the measurement with the same setup on the Oasis measurement system.

4.1.1 Run Chart and Individual Chart

As mentioned in Section 2.3.2, in order to achieve excellent sealing performance, surface finish and threading pitch diameter are the most critical dimensions. Also, from Section 2.3.3 and 2.3.4, thread insert break is the most frequent failure mode in production. Compared to surface finish, the pitch diameter of the thread is easier to monitor and control by SPC control chart tools, so pitch diameter is the main focus for Chapters 4, 5 and 6.

Run charts of baseline data of each of the two part orders in the pitch diameter were plotted to demonstrate the tendency of the data in time sequence as shown in Figure 13 (a) and (b), respectively.

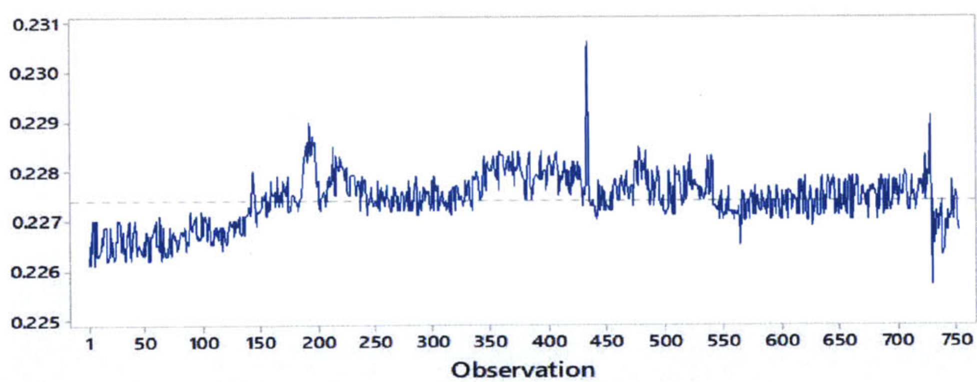


Figure 13 (a): Run chart of the first order, approximately 750 parts of initial baseline data collection of pitch diameter of pitch diameter.

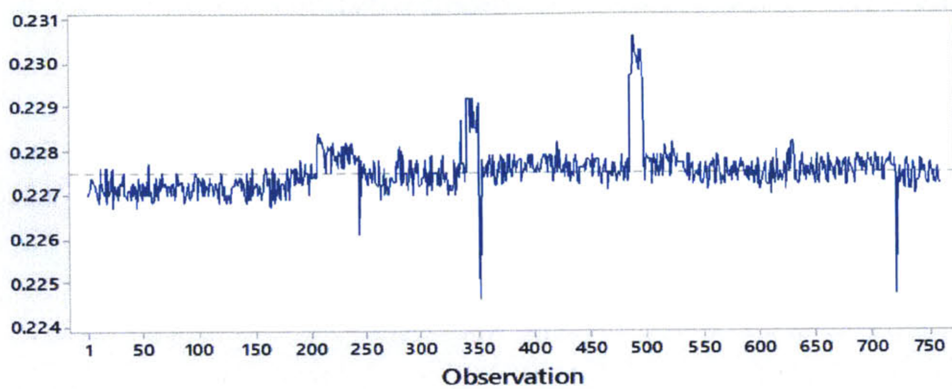


Figure 13 (b): Run chart of the second order of approximately 750 parts of initial baseline data collection.

We can see from the plot that there were roughly 750 parts produced in each order. The dashed line in the plot is the grand mean of the process. The grand mean is 0.2274 for the first order and the grand mean is 0.2275 for the second order. Grand means are next compared to the design specification. The specification of the pitch diameter is 0.2255 to 0.2287 with a nominal value of 0.2271. Therefore, both orders have a slight mean shift from the target that is less than 0.0005 inches.

Control charts were plotted to determine whether the process is in statistical control or not. Since the process is continuously running, there is no clear subgroup in which each part is produced in exactly the same condition. Therefore, we choose subgroup size to be 1. Since there is no sampling applied to the data collection in this phase of the project, we are collecting 100% inspection data. Therefore, only individual charts are applied, which are shown in Figure 14 (a) and (b) for the two orders, respectively.

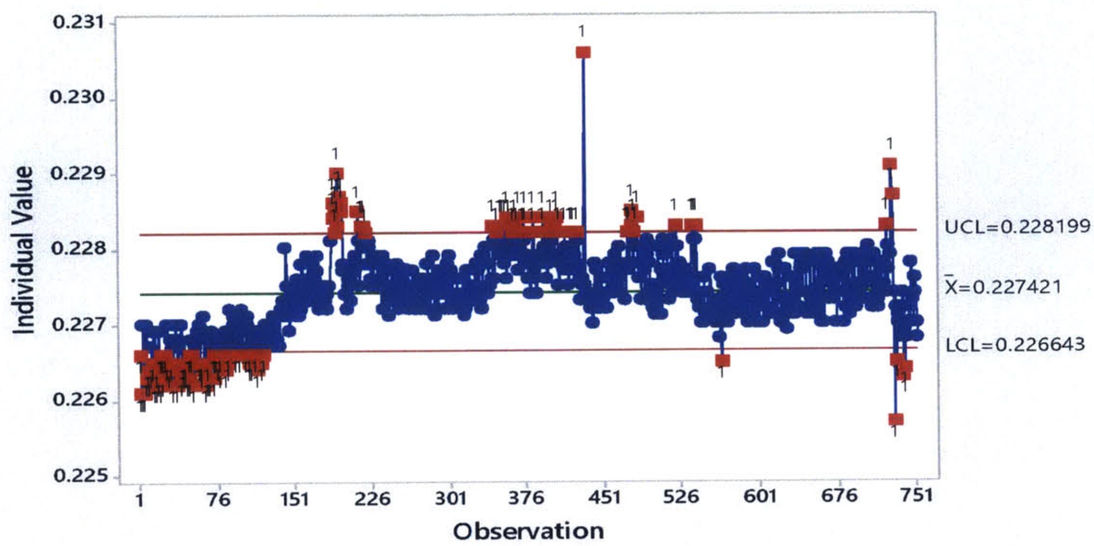


Figure 14 (a): Individual chart for the first order demonstrating that the process is out of statistical control.

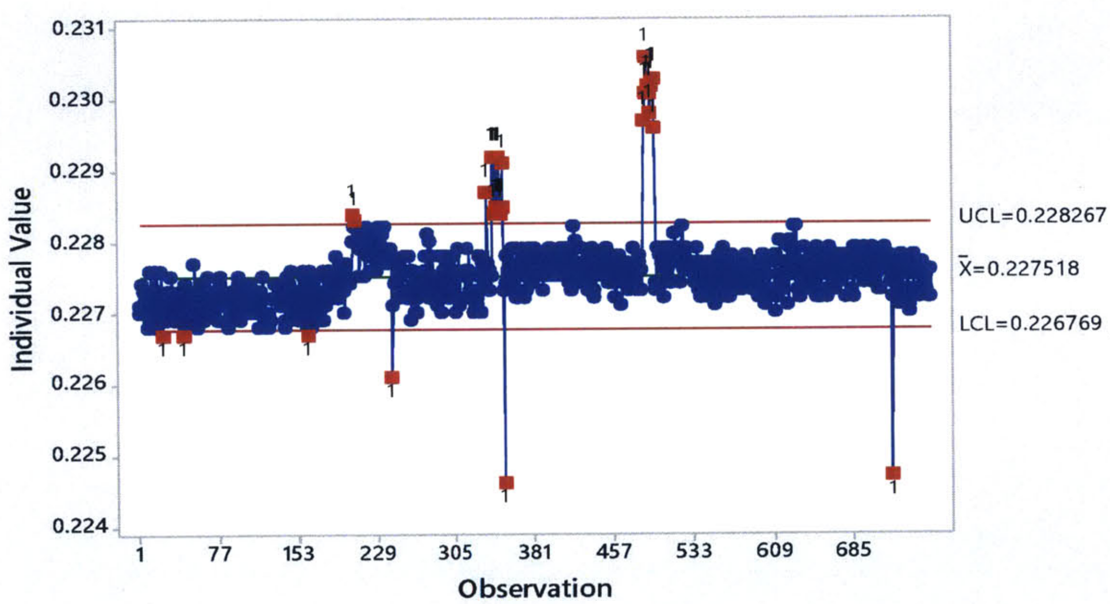


Figure 14 (b): Individual chart for the second order demonstrating that the process is out of statistical control.

As mentioned in Section 3.3, in order to use control charts to monitor the process and reduce scrap rate, the process needs to be in statistical control. In order to bring the process back into control, root causes need to be analyzed and their corresponding reaction plans need to be implemented and proved. From the individual chart, we only know that the process is out of control but there is no information linking the data to the events that happened in the process. Therefore, a qualitative, instead of quantitative, root cause analysis was conducted based on experience of the operators and engineers.

4.1.2 Qualitative Root Cause Analysis Based on Experience

From the data, there are four major tendencies indicating the process going out of control: single peak up, single peak down, sudden mean shift and gradual mean shift, which are shown in Figure 15.

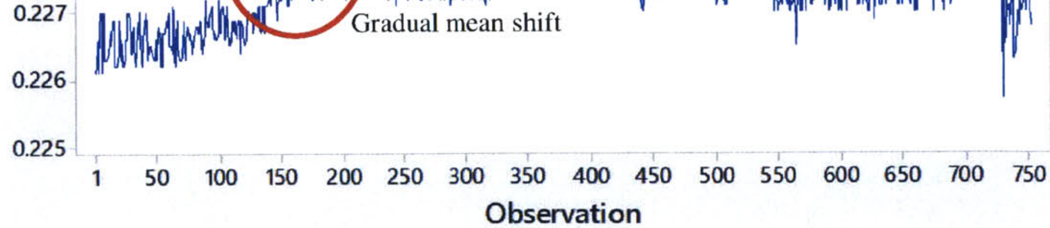


Figure 15 (a): Qualitative root cause analysis based on experience.

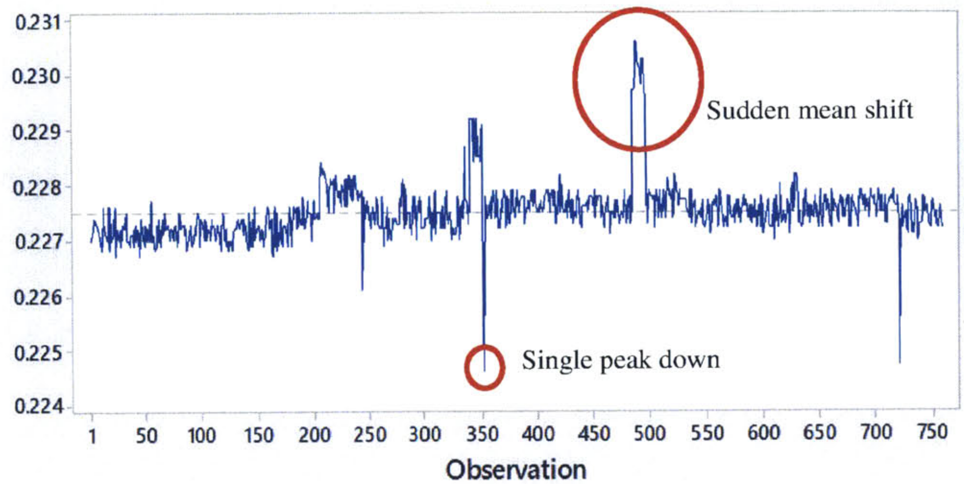


Figure 15 (b): Qualitative root cause analysis based on experience.

Based on interviewing the operators and engineers, opinions are summarized in Table 3. Four major failure modes, potential causes, reaction plans and information sources are included in the table. Causes are ranked based on how many people agree with each of them. For example, two operators agree that tool break is the cause of data showing single peak up and one operator believes that other reasons cause this data tendency. Therefore, tool break is ranked ahead of other potential causes.

Table 3: Root cause analysis based on experience.

Failure Mode	Cause	Reaction Plan	Voice
Single Peak Up	Tool break	Change tool	Steve, Dennis
	Measurement mistake	Re-measure it	Leo
	Operator change	None	Debbie
	Machine stops such that engine oil gets cold	Watch machine closely, wait until it warms up	Rogelio
Single Peak Down	Chip accumulation	Blow chip away	Steve, Dennis, Rogelio
Sudden Mean Shift	Tool break	Change insert	Leo, Steve, Dennis
	Threading insert tool wear	Change insert	Rogelio
	Collar loose	Tighten collar	Debbie
Gradual Mean Shift	Tool wear	Offset	Steve, Dennis, Rogelio
	Threading insert not aiming the correct direction	Adjust insert	Rogelio
	Material difference between bars	None	Dennis

Since there is no evidence to prove which cause is the root cause for each failure mode, we cannot make the corresponding decision to bring the process back into control. Therefore, the experience based root cause analysis can only be used as references of potential causes for each failure mode. Those potential causes will be monitored with extra care and recorded with time, part number, details and comments using event recording method for troubleshooting as mentioned in Section 3.3.1.

4.2 Second Baseline Data Collection

In the previous section, initial baseline data was collected, charts were plotted and qualitative root cause analysis was conducted. But there is no conclusion made in the end of root cause analysis because there is no method to prove that the analysis result and the reaction plan is correct. Therefore, event-recording, was added and applied as discussed in Section 4.2.1 to link the events with production problems shown in the data, as it is the easiest way to uncover the obvious assignable causes in the process. A second baseline run of 1500 parts was then produced. Based on data analysis, as discussed below in Section 4.2.2, tool offset and tool change were determined to be the most common assignable causes that bring the process out of control. As a result, standard operating procedures (SOPs) to tackle these two causes were designed and documented. Training of these SOPs for the operators was conducted step by step to ensure that they are following the standardized way of changing tools and giving offsets.

After the SOP was conducted and the process was brought back into control as discussed below in Section 4.2.3. An inspection sampling plan was then determined as described in Section 4.2.4, this plan is mainly based on the capability of the operator to ensure there are enough data points to monitor the process, but such that inspection does not add too much extra work for the operators.

4.2.1 Event Recording

As introduced in Section 3.3.1, event recording is a method to record any changes on operator made during the production. It helps the engineers to better understand what has been changed before and after a production defect happens. It also provides the possibility to link the data with production events such as tool break, tool wear, surface finish too good or too bad and when those events happened. Initially, for the convenience of engineers, event recording was documented on a sheet of paper and then an Excel sheet was created to summarize the critical results and ignore unimportant ones. An example of event recording paper is shown in Figure 11 and the Excel sheet of the second baseline run is shown in Table 4.

Table 4: Example of event recording Excel sheet for the first 100 parts in the first order.

Part No	Time	Tool Change	Offset	Notes	Operator
Setup	8.28am	turning, threading, cutoff on both sides and end mill, new guide bushing			Steve
1	9:40am		1. Offset for threading tool +0.001 in PD 2. End mill offset by +0.002	1. No go goes, need PD offset; 2.Flat thickness 0.1838 too small, need end mill offset	Steve
2	9:42am		Increase main feed rate from 0.005ft/rev to 0.006ft/rev	Main-side surface finish 22, too good	Steve
4	9.45am		1. Decrease main feed rate from 0.006ft/rev to 0.0057ft/rev 2. Increase sub feed rate from 0.0037 to 0.0039 ft/rev	1. Main-side surface finish 30, not good enough 2. Sub-side surface finish 23, too good	Steve
6~10				Parts are not in time sequence	Steve
55	12pm			Quick check- Main Side-OD-0.2054 , MD-0.2463 Subside- OD - 0.2047, MD- 0.2454, Flats- 0.1862, Surface finish(MS)- 24.88, (SS)- 25.12	Steve
LUNCH BREAK					Steve

In this example, initial setup included new tools setup, which was done at 8:28 in the morning by the operator Steve. Since the pitch diameter of the thread and surface finish are the most critical dimensions for the entire part, the operator kept monitoring the pitch diameter of the thread on the go and no-go gages as well as on the Johnson gage to ensure that they are close enough to the designed nominal value. The go and no-go gages, shown in Figure 16 are used to check whether the pitch diameter is within design specifications. For example, in the first part, the pitch diameter of the thread is too small because the no go gage goes. This result was confirmed in the Johnson gage, which is shown in Figure 17. Therefore, the operator provided an offset on the position of the threading insert to bring the tooling to the right starting position. This dimension was measured again on the Johnson gage for the next part to ensure that the offset as a reaction plan did help to bring the pitch diameter of the thread close to the nominal value.

Figure 16: Quick check tools including blade micrometer, regular micrometer and go and no-go gages from left to right.

Figure 17: Johnson gage used to measure pitch diameter of thread.

The operator also inspected the surface finish under the profilometer, shown in Figure 18, which is a measuring instrument used to quantify the surface roughness. For example, in the second part, the surface finish is 22, which is in the lower end of the specification range and below the nominal value. This means the surface finish is better than what is needed from the design perspective. Therefore, the operator increased the feed rate from 0.005 feet per revolution to 0.006 feet per revolution. Then he measured the surface finish again on the next part to confirm that the increase in feed rate as a reaction plan did help to bring the surface finish close enough to the designed nominal value.

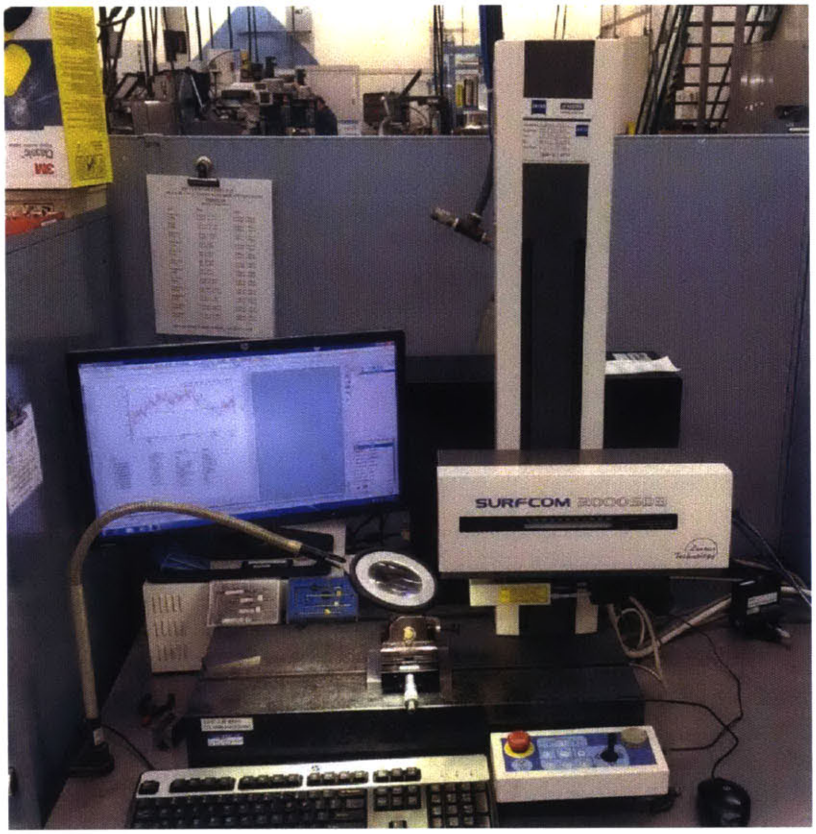


Figure 18: Profilometer to inspect surface finish and generate its corresponding report.

After producing the 12th part, the process was stable and all dimensions were close to the nominal values. The operator kept doing regular quick inspection every 20 parts to ensure the most common failure modes did not happen. After part number 65, the operator went for lunch break while the production continued running. When the operator came back, he checked the first part to confirm that all critical dimensions were close to the nominal values.

The two orders of 1500 parts in total took around 36 hours. Therefore, the three of us in this thesis project team took three shifts to work continuously in the machine shop, monitor the production process, record all relevant events and organize the data into the excel sheet from part 1 to part 1500.

4.2.2 Observations from the Run Chart and Individual Chart

The run charts for the second baseline run are plotted separately to monitor the process and visualize the assignable causes as shown in Figure 19 (a) and (b). This same data is plotted again in the individual charts of Figure (c) and (d) respectively, but with control limits and out of control points indicated.

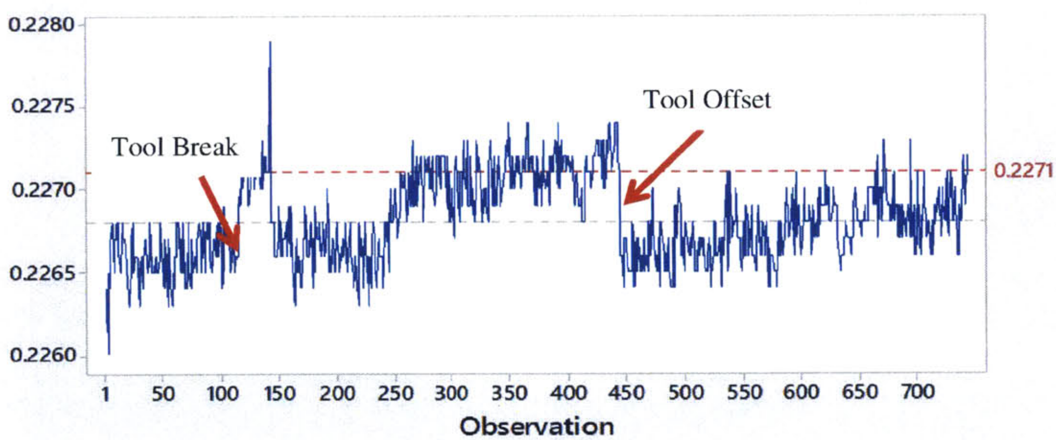


Figure 19 (a): Run chart for the first order of the second baseline data collection.

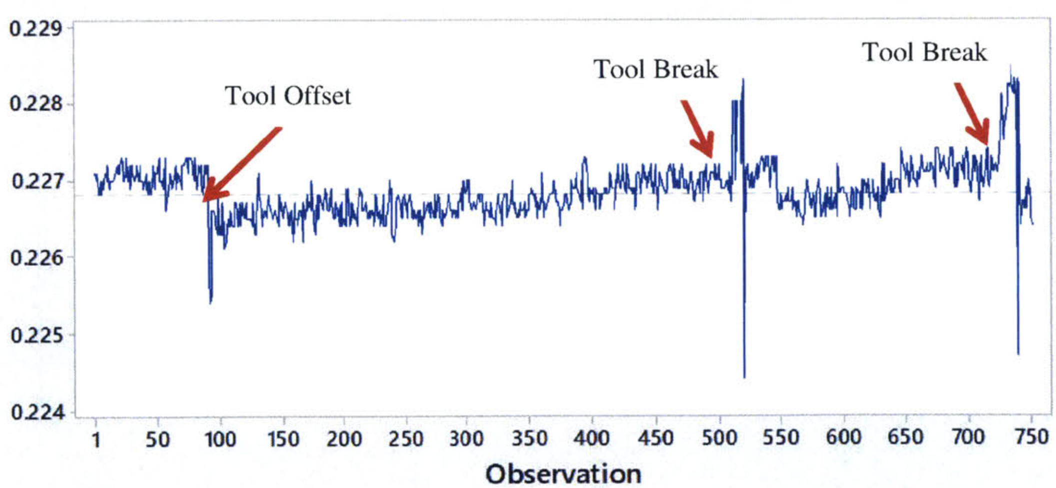


Figure 19 (b): Run chart for the second order of the second baseline data collection.

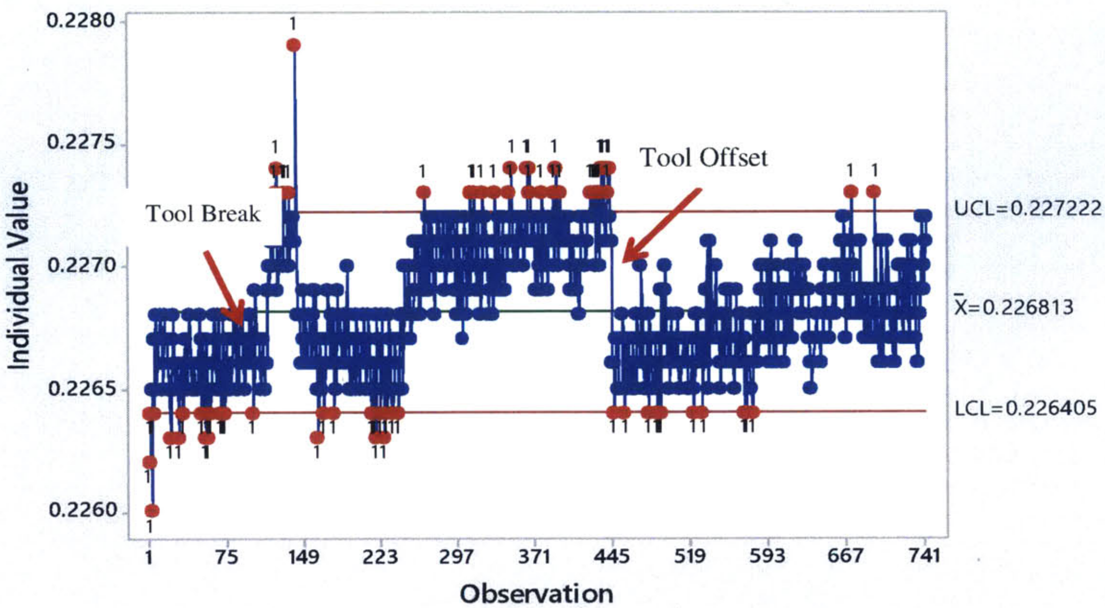


Figure 19 (c): Individual chart for the first order of the second baseline data collection

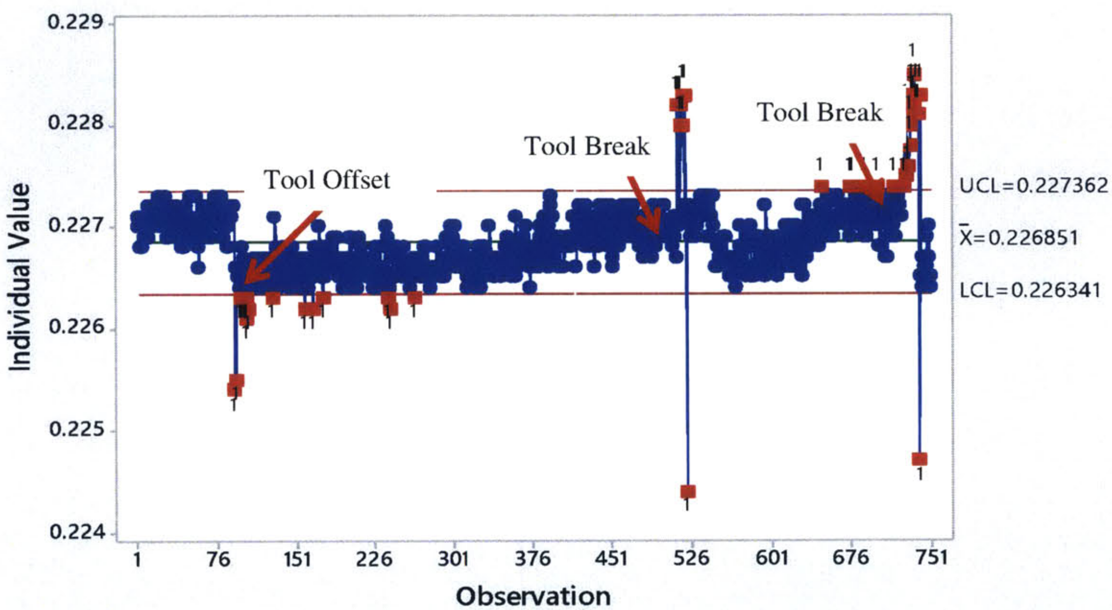


Figure 19 (d): Individual chart for the second order of the second baseline data collection

When we applied Western Electric Rules [10] mentioned in Section 3.2.2, we found that there are certain ranges on both orders that are out of control. For example, in the first order, points that are out of control were marked in red. Obviously, based on Rule 1, the process at those points is out of control. Also, from point 593 to 741, there is a constant small slope of mean shift. Based on Rule 5, the tendency indicated that the process is out of control. There is high possibility that this was due to the tool wear. In the second order, the process became much steadier. Because of the tool wear, from point 300 to point 500, there is a constant mean drifting, which indicates that the process is out of control based on Rule 5. Again, from point 676 to 751, there are several points that went beyond the control limits, which indicated that the process was out of control based on Rule 1.

Major events including tool change and tool offset were marked onto the run chart and individual chart. From the plots, the events match the data perfectly and this further confirmed some of the conclusions made in the qualitative root cause analysis in Section 4.1.2.

There is other valuable information that can be obtained from the control chart. First of all, in the first order, the production began with a constant mean shift and stayed there until the event of tool break. After changing a new tool, from part 150 to part 250, the operator set the position below the nominal value and kept production running. The operator tended to set up the tool to the position below nominal because of his experience, the distance of the mean shift can compensate the threading insert tool wear. It was a pure experience-based decision without any data support. Therefore, it is a good example of how a control chart can help the operator to make a data driven decision. To avoid such a mean shift, a standard operating procedure was designed and the operator was trained to set up the production right on the nominal value. A real time inspection is needed such that only when the operator observes the process going out of control can he give an offset to bring the process mean back to the nominal value. Details about real time inspection will be discussed in Section 4.3.

Another interesting observation from the control chart is that the slope of the tool wear (tool wear speed) is not constant. For example, in the first half of the first order, there is almost no tool wear at all. However, starting from point 445, there is a relative high speed of tool wear although the same tool is being used in the same machining situation. Also, in the second order, there is a relative low speed of tool wear throughout the production. Since there are many factors like machining vibration, temperature, pressure and slight coolant flow rate difference that we are unable to control with high precision, it is hard to conclude which factor contributes to the tool wear speed difference the most. From another point of view, tool wear is a natural existing fact that we cannot get rid of. So we have to better understand its behavior and ignore it when we judge whether the process is in statistical control or not. Better understanding of the tool wear can be done by a factorial Design of Experiment (DOE) as mentioned in Section 3.3.1. Since this thesis focuses on the application and importance of control chart instead of troubleshooting, this will be discussed in Section 6.2 as part of future work and recommendations.

Lastly, there are still some unknown assignable causes that need further investigation. For example, in the first order from point 223 to point 297, there is a strong constant mean shift up. From event recording, the operator did not do anything during that time. Also the slope of the mean shift is much higher than that of tool wear. Therefore, there must be something inside the process other than tool wear happening only for those points. Since troubleshooting from operator experience interviews and event recording does not uncover the root cause behind this assignable cause event, further work needs to be conducted, which will also be discussed in Section 6.2.

4.2.3 Bringing the Process Back into Statistical Control

In order to bring the process back into control, all assignable causes need to be eliminated. From the event recording, we already know the obvious assignable causes such as tool break. Therefore, it was quite easy to develop a reaction plan and an SOP to deal with those causes. Tool change is used to react to tool break and tool offset is used to compensate for the tool wear. Details about how the SOP was developed, what are the procedures of SOP and how it is implemented in production can be found in Udayshankar's thesis [2].

Once the SOP has been developed and the operators have been trained, we are confident in the operator's ability to eliminate the assignable cause due to tool break and compensate the assignable cause due to tool wear by tool offset. Thus, the process can be bought back into control. This enabled us to calculate the process capability Cpk value and determine the sampling plan for the real time inspection, assuming theses assignable causes have been eliminated. As a result, reaction plans are verified by the fact that the process is then in statistical control. Since the control limits are always much tighter than the specification limits, out-of-spec defects can be reduced by the proven reaction plan.

4.2.4 Sampling Plan Determination

In order to use control chart to monitor the production, sampled inspection is essential. The 100% inspection is ideal theoretically but is hard to achieve in a fast-paced machining center. Therefore, a proper sampling frequency is needed to ensure that enough data is collected and not too much extra work is added to the operators.

After discussion with operators and engineers, a sampling frequency of 20 was determined. Because of the sampling, there is some risk of around 10 defects in average before an out-of-control point is detected. To compensate it, we recommended a quick inspection on critical dimensions with go and no-go gage and micrometer on a sampling frequency of 10. We applied the full inspection sampling plan of 20 and quick inspection sampling plan of 10 onto the second baseline data run chart and found that all assignable events and tendencies could be captured. Also, from the Gage Repeatability and Reproducibility (Gage R&R) study in Zhang's work [1], especially from the new fixture design, the inspection cycle time was reduced from 31 minutes and 30 seconds to 1 minute and 30 seconds. Since the column production cycle time ranges from 60 seconds to 100 seconds, 1 minute and 30 seconds of inspection out of 10 parts' production time can be handled by the operator with no difficulty.

After the inspection SOP was developed by Udayshankar [2] and training completed with the operators, ease of inspection operation and precise inspection results were ensured. Therefore, operators were satisfied and able to apply the inspection sampling frequency, and are ready to use the control chart to monitor the production process in real time.

4.3 Real Time Inspection with Sampling

ProLink is a data collection and SPC analysis software system that is currently used in the Waters machining center. By one click on the data collection hardware module, readings from the inspection gage can be imported into the QC Calc Real Time software module. Again, since the pitch diameter is one of the most critical dimensions and it is easy to monitor using control chart and SPC tools, this section will focus on the pitch diameter of the thread. An example of the control chart user interface of the software is shown in Figure 20.

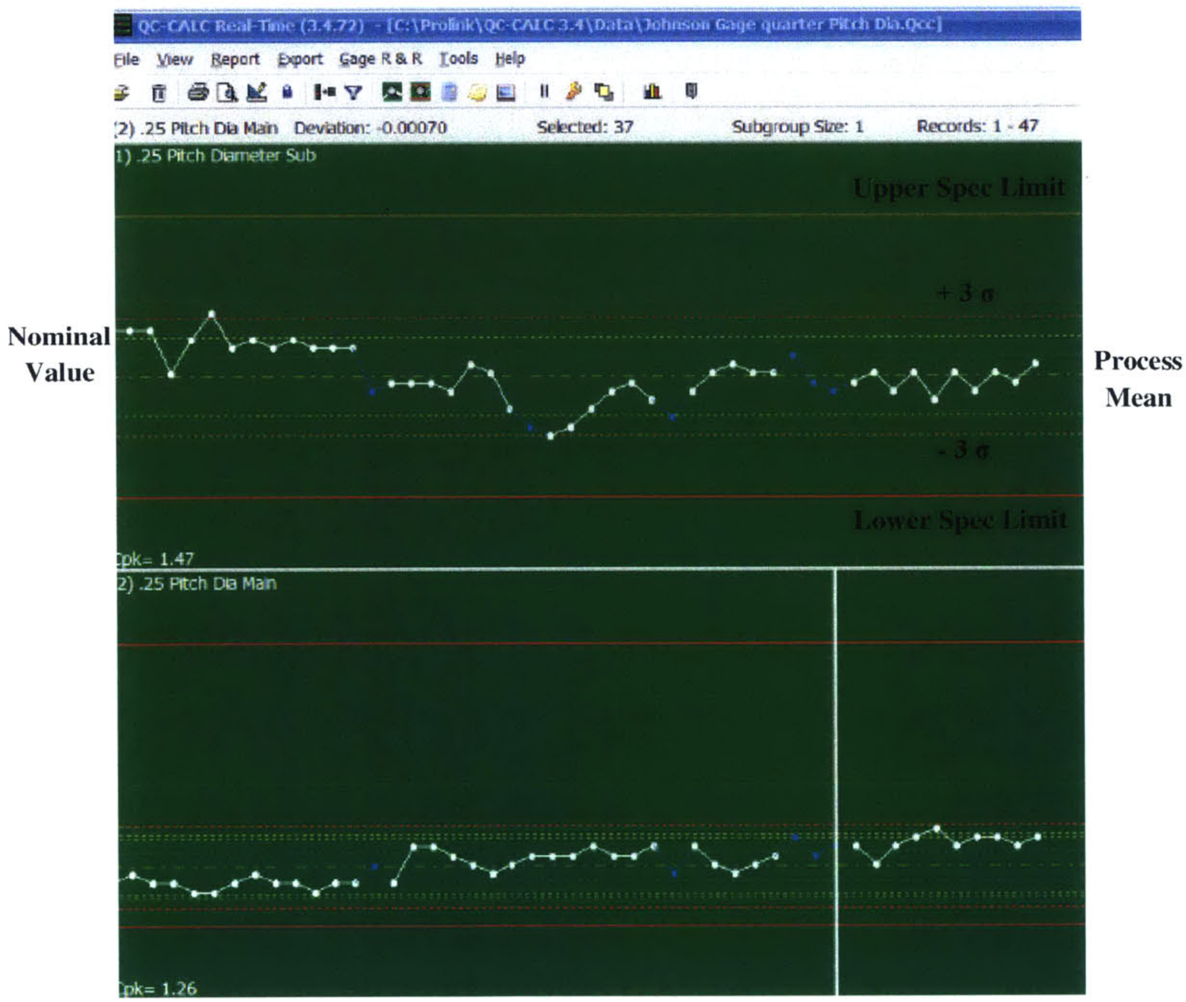


Figure 20: Control chart function in the ProLink software as a real time inspection tool.

To keep the consistency of the type of control chart, the individual chart was used in ProLink. The meaning of each line is shown in Table 5.

Table 5: ProLink software lines layout.

	Type of Lines	Representations
1	Red Solid Line	Upper/Lower Specification Limit
2	Green Solid Line	Nominal Value from Design Specification
3	Longer Green Dashed Line	Process Grand Mean
4	Red Dashed Line	Upper/Lower Control Limits ($\pm 3\sigma$)
5	Shorter Green Dashed Line	$\pm 1\sigma$, $\pm 2\sigma$
6	White Vertical Line	Event with Notes

Notice that two pitch diameters are measured and shown in Figure 20, one is for the sub-side of the column and the other is for the main-side of the column as defined in Figure 2. White dots on the charts are data points collected from the Johnson Gage. The control limits are calculated based on the first 10 parts after the production process is stable. Whenever there is an offset or tool change made by the operator, the control limits need to be calculated again. The formulas to calculate the control limits embedded in the ProLink software are identical to those in Minitab, details on these formulas are provided as Equation 3.1 to 3.6 in Section 3.1.2.

This real time control chart also allows the operator to record events using white lines and notes on the graph. Whenever there is an assignable cause event such as tool break, operators can mark the time spot of the event with details recorded in the note. This is a perfect integration of the event recording sheet into the control chart SPC tool, making it more convenient for the engineers to conduct troubleshooting and root cause analysis. An example of sub-side tool offset is shown in Figure 21. This occurs at part number 35 where an offset was set to bring the pitch diameter dimension back to the designed nominal value of 0.2271. Figure 22 shows that when recording events, the operator can choose from the events that have already happened in the past. The more frequently the event happens, the higher it shows up in the available causes list.

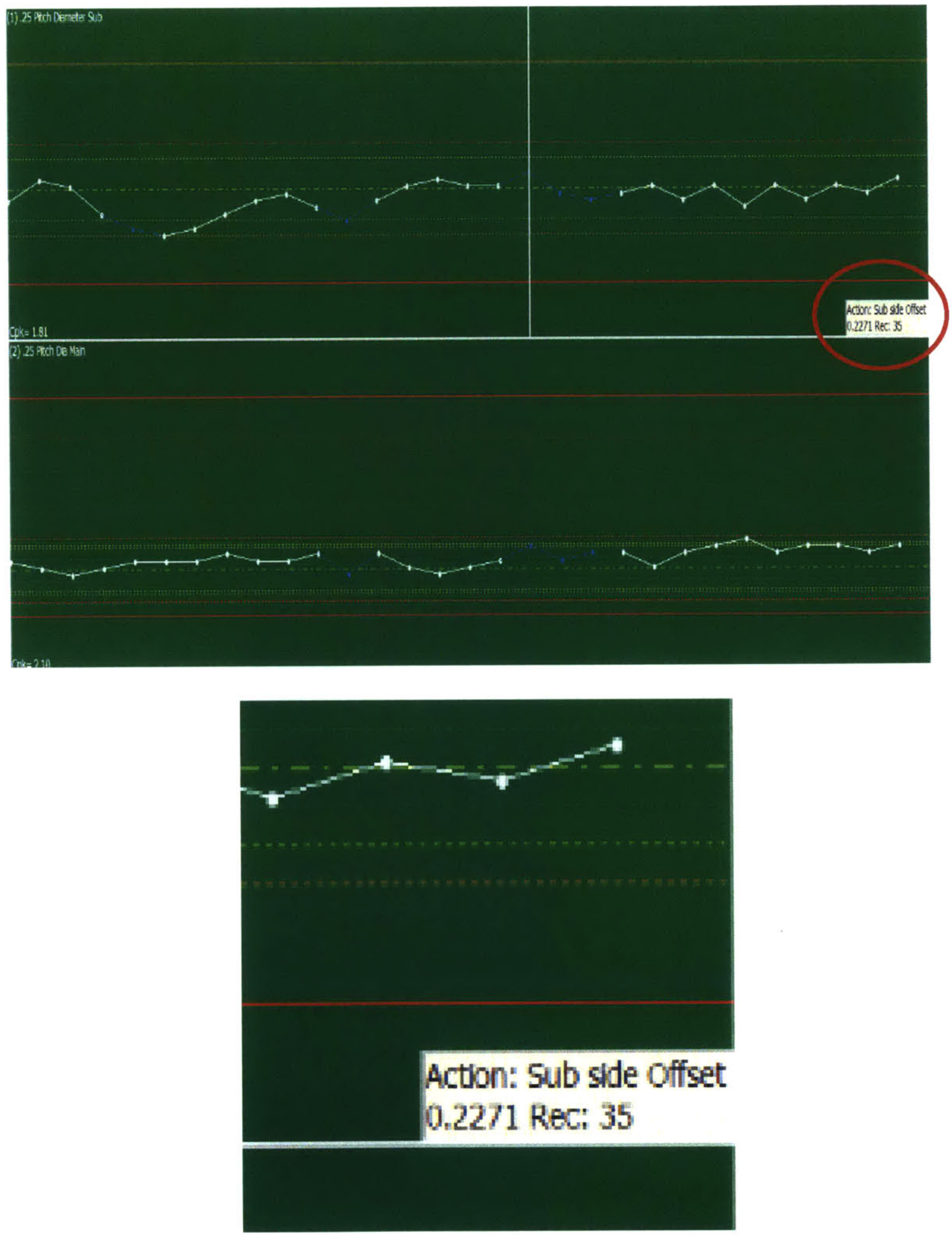


Figure 21: Real time inspection event record notes embedded in the ProLink software.

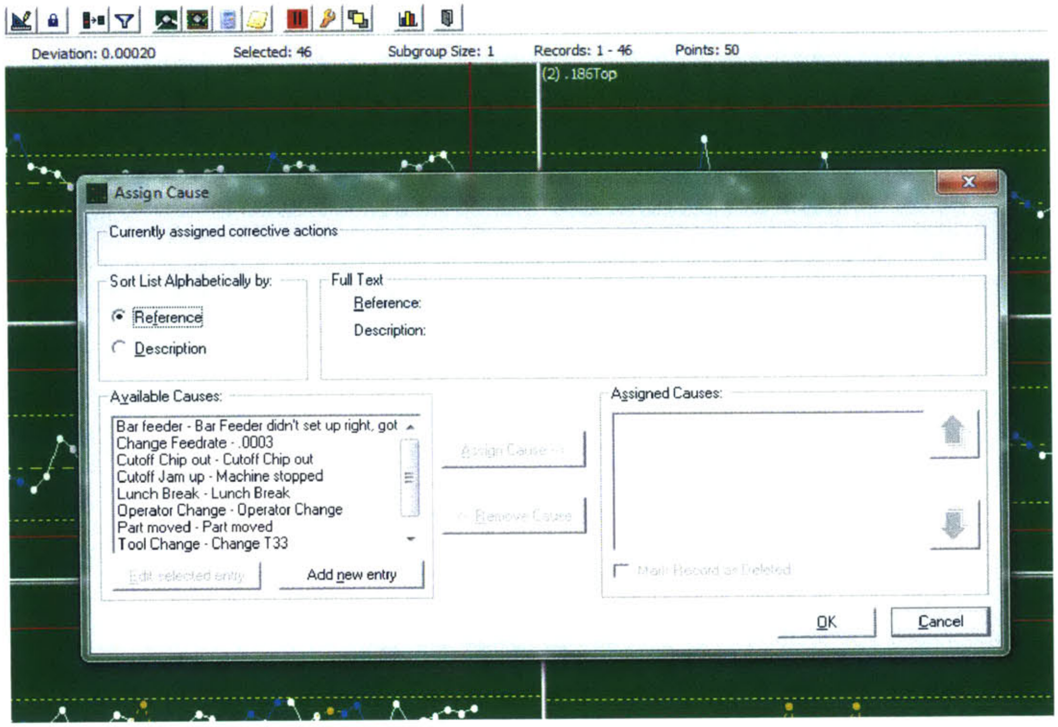


Figure 22: Assign cause dialog window to enable the operator to record production events.

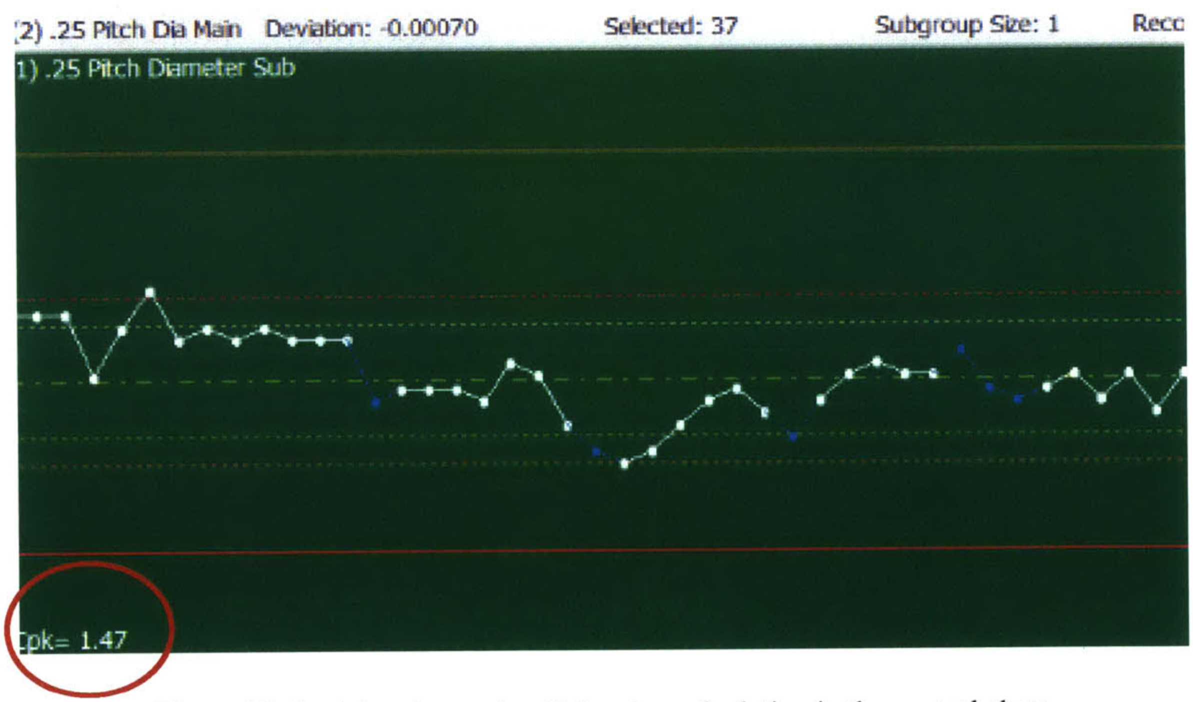


Figure 23: Real time inspection Cpk value calculation in the control chart.

Lastly, the process capability index Cpk value is also calculated automatically by the software. The formula used in ProLink is shown in Equation 2.1. In the previous example, Figure 23 shows that the Cpk value for the pitch diameter is 1.47, which is above 1.33. It indicates that the process capability is in good condition. However, from a continuous improvement perspective, a higher Cpk value can be achieved if the process mean can be brought closer to the nominal value, and if the natural cause variation can be made smaller.

Cpk can be important to different stakeholders. Engineers care about the process capability which can be easily quantified by Cpk value. In order to develop the company into a world class manufacturer, six sigma level of process capability is a must. Managers' point of view often considers the company reputation and customer satisfaction. Cpk values are automatically included in the quality report and stored in the company's SAP database system. Through SPC long term monitoring and continuous manufacturing process improvement, higher values of Cpk will be achieved, which is strong evidence of higher quality of the products. This will surely improve the company's reputation with customers.

Although it is quite convenient to plot the control chart and use it to monitor the process, an exported data in Excel sheet is a better format to save the data in the SAP system and thus share with other engineers to better communicate technically. Table 6 is an example that demonstrates the format of data exported from the ProLink software package.

Table 6: ProLink exported data to keep record of production process monitor.

_25 Pitch D	_25 Pitch D	Date_Time	Fails	Assignable	Assignable	Corrective /	Corrective Action2	
0.2274	0.226	7/7/2015	0					
0.2274	0.2261	7/7/2015	0					
0.2274	0.226	7/7/2015	0					
0.2269	0.226	7/7/2015	0					
0.2273	0.2259	7/7/2015	0					
0.2276	0.2259	7/7/2015	0					
0.2272	0.226	7/7/2015	0					
0.2273	0.2261	7/7/2015	0					
0.2272	0.226	7/7/2015	0					
0.2273	0.226	7/7/2015	0					
0.2272	0.2259	7/7/2015	0					
0.2272	0.226	7/7/2015	0					
0.2272	0.226	7/7/2015	0					
0.2267	0.2262	7/7/2015	0	Operator Change				
0.2268	0.226	7/7/2015	0					
0.2268	0.2264	7/7/2015	0					
0.2268	0.2264	7/7/2015	0					
0.2267	0.2263	7/7/2015	0					
0.227	0.2262	7/7/2015	0					
0.2269	0.2261	7/7/2015	0					
0.2265	0.2262	7/7/2015	0					
0.2263	0.2263	7/7/2015	0					
0.2262	0.2263	7/7/2015	0					
0.2263	0.2263	7/7/2015	0					
0.2265	0.2264	7/7/2015	0					
0.2267	0.2263	7/7/2015	0					
0.2268	0.2263	7/7/2015	0					
0.2266	0.2264	7/7/2015	0					
0.2264	0.2261	7/7/2015	0	Lunch Break				
0.2267	0.2264	7/7/2015	0					
0.2269	0.2262	7/7/2015	0					
0.227	0.2261	7/7/2015	0					
0.2269	0.2262	7/7/2015	0					
0.2269	0.2263	7/7/2015	0					
0.2271	0.2265	7/7/2015	0			-0.0003		

All information is recorded in the Excel sheet including inspected dimension, pitch diameter in this case, inspection time, failure or not, any assignable cause and corrective action (reaction plan).

4.4 Long Term Monitoring

The individual control chart implemented in the ProLink software enables real time inspection and monitor in the machining center. The good process capability and fewer assignable causes indicates that the control chart does help the operator to better control the machining process and improve the production quality. However, only one example is not convincing enough to demonstrate to all stakeholders the strong capability of the control chart tool. Therefore, the same ProLink individual control chart was applied to other two different column families and applied to critical dimensions other than pitch diameter of the thread for long term monitoring.

The Oasis is a smart automatic inspection system that operates by casting a shadow of a part to be inspected and capturing that image in a digital format. The digital image is analyzed by powerful software behind the scenes and is converted into real dimensional data that measures the part accurately. Figure 24 shows components of an Oasis System.

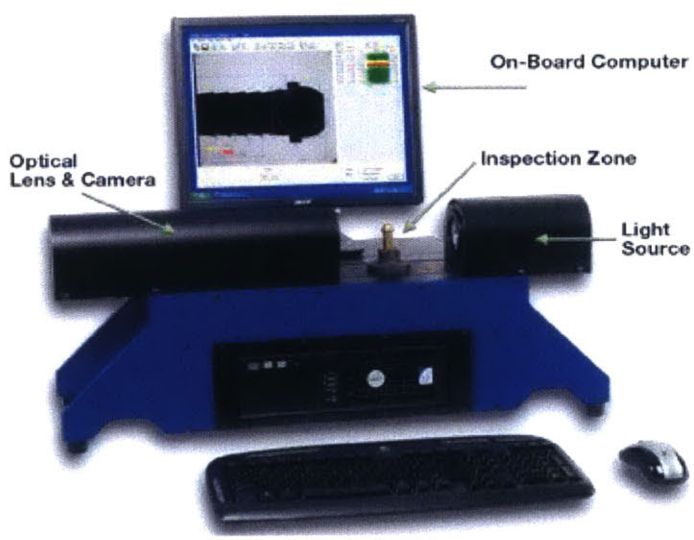


Figure 24: Components of the Oasis system [12].

Figure 25 demonstrates the application of ProLink individual control chart on the Oasis system to inspect the dimensions of a wrench flat, turning profile and column outer diameter. Figure 26 demonstrates the control chart data collection program embedded in the Oasis system.

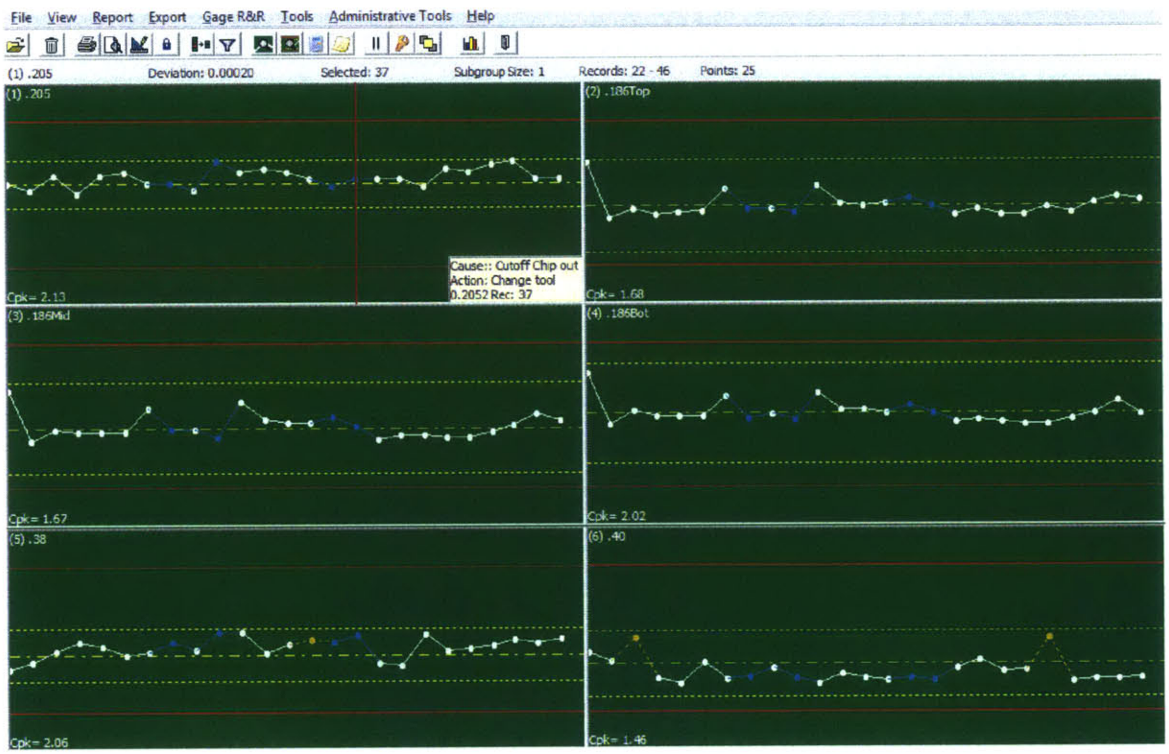


Figure 25: Long term monitoring using individual control charts in the Oasis system for multiple inspection dimensions.

Notice that since there are six dimensions that are measured in the Oasis system, there are six corresponding individual control charts viewed in the ProLink Software. As mentioned in Section 4.3, assignable causes are labeled onto the control chart and Cpk values for each dimension are calculated. For all dimensions listed in this example, the Cpk values are greater than 1.33, which further shows that the process capability for dimensions other than pitch diameter are good.

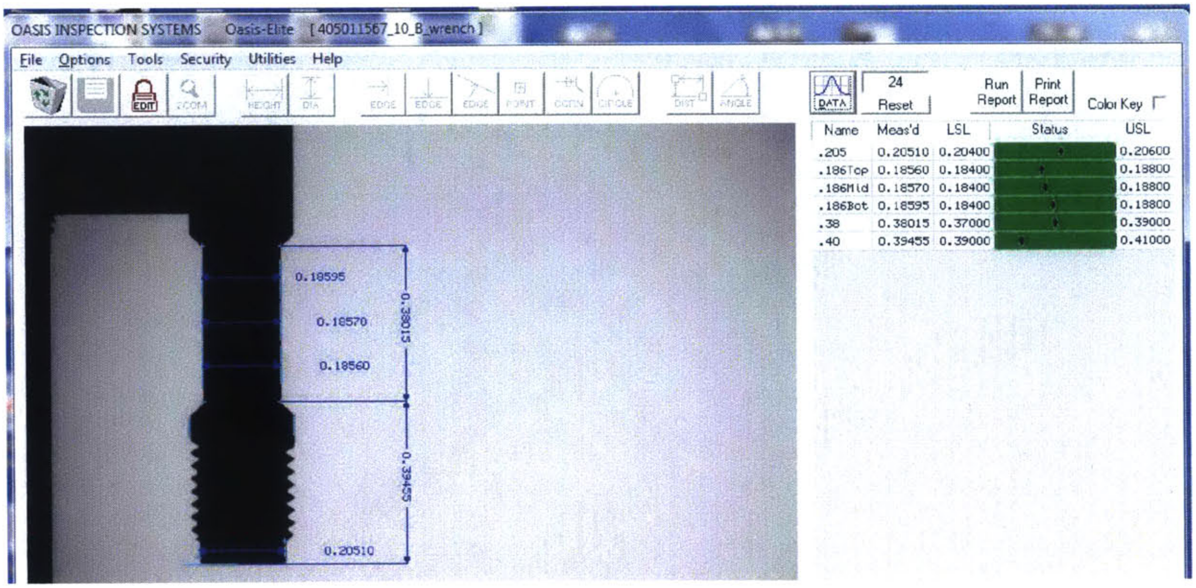


Figure 26: Oasis system user interface to collect inspection data for dimensions relevant to wrench flat, length and outer diameter.

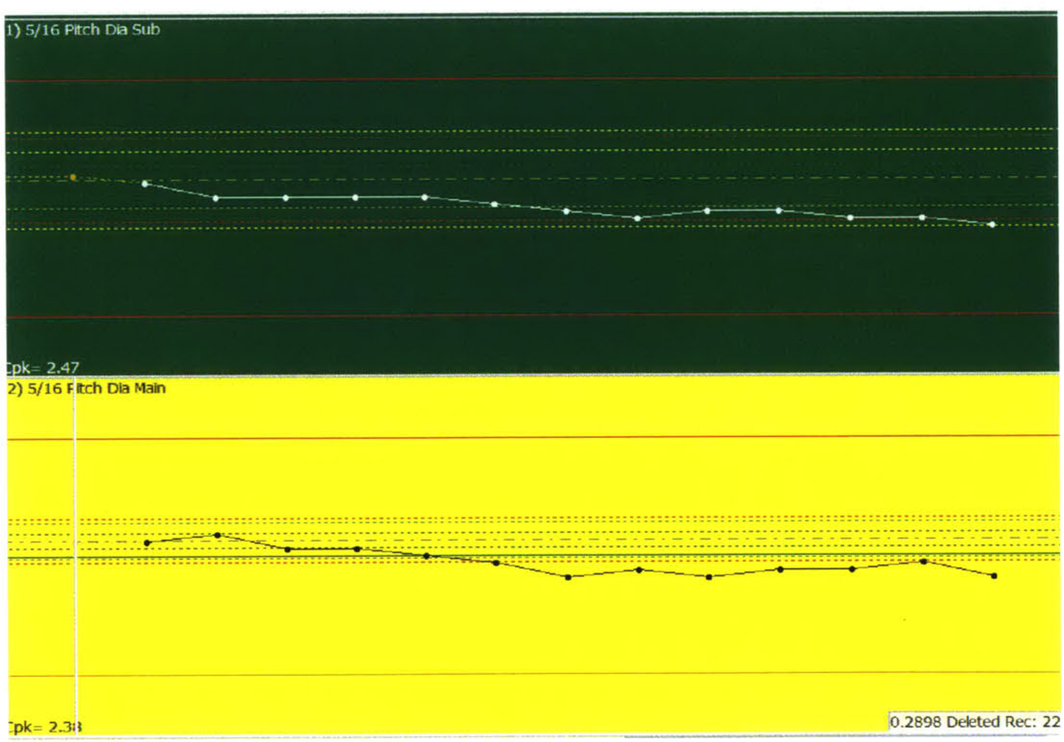


Figure 27: Application of control charts to long term monitor the pitch diameter of the 5/16" diameter column families.

Figure 26 and Figure 27 together show how a control chart is integrated with the Oasis system. Figure 26 is the window from the Oasis system itself to collect inspection data, and shows where the measurement is located relevant to the specification limits. Details about what the Oasis system is, how it works to conduct inspection and what fixture our team designed to improve its gage capability and performance can be found in Zhang's Gage R&R study [1].

Another benefit of using ProLink is that we can set the Western Electric Rules from Rule 1 to Rule 4 in the software. When the process goes out of control, the background of the chart will suddenly turn from green to yellow as shown in Figure 25, which warns the operator to record the assignable cause, implement the corresponding reaction plan and monitor the next part to bring the process back into statistical control.

From the fact that the operator is able to bring the process back into control right after the process went out of control and the resulting high process capability Cpk value, we are confident that the individual control chart is indeed a powerful tool to achieve real time inspection and prevent the production going out of specifications. Defects due to product characteristics going out of specifications are largely reduced or even eliminated.

The entire ProLink and control chart system will remain in the column area of the machining center to monitor the machining process over the long term to ensure a world class manufacturing capability. The value created by this control chart and SPC implementation will be discussed in detail in Section 5. In the future, the long-term monitoring process will also be scaled up to the entire Waters machining center to improve the production quality in other areas such as NC turning area, valve area and NC milling area.

As a result, by eliminating assignable cause variation, continuous improvement of the process can be achieved to help Waters Corporation become a world class manufacturer with high production quality and excellent customer reputation.

5 Results and Conclusions

This chapter focuses on results and discussion of control chart application in the Waters machining center. First of all, the individual control chart helps the machining center to achieve real time inspection, which allows the operator to better monitor the process and control the production quality as discussed in Section 5.1. Secondly, production defects are reduced due to the application of control chart as presented in Section 5.2. Lastly, a brief calculation is conducted in Section 5.3 to estimate the dollar value of potential annual savings created by the control chart application.

5.1 Real Time Inspection

As noted in the problem statement section, one of the main purposes of this thesis project is to introduce a real time inspection tool that is easy to use and provides accurate data to monitor the production process in the machining center. Experienced operators can apply this tool to better control the production quality and new hired operators can also learn how to use this tool within a short period of time to achieve similar results as do experienced operators.

Real time here means once a part is inspected, the corresponding data shows up immediately in the control chart. With the control limits calculated from the initial setup, the operators can easily see the position of the data located in the range of control limits as well as design specifications. Since the Western Electric Rules [10] are already integrated into the ProLink software, warnings of a data point going out of statistical control will automatically show up whenever they happen. Therefore, the operator does not need to do extra work to judge whether the process is in control or not. He only needs to include the events and reaction plan into the program to help build the root cause analysis database.

Besides ease of operation, it also helps new hires to standardize their quality control methodology. All of them will use the same control chart tool and follow the same standard operating procedures (SOPs), which will surely reduce the extra variation introduced from operator to operator. The real time control chart will also help them make data driven, rational and convincing decisions.

5.2 Defect Rate Reduction Due to Application of Control Chart

Besides control chart acting as a powerful real time inspection tool, the active use of the control chart also helps reduce production defect rate. From the data obtained from the engineers, the scrap rate for column area last year is 8%. After our data collection of failure modes and the frequency of each failure mode, we found that 50% of the defects could be solved by the SPC control chart implementation. Failure modes frequency distribution can be seen from Figure 5. From the chart, the most frequent failure modes, tool change, threading, setup and tool wear can be better managed by SPC implementation. For example, tool break happens with lower frequency, tooling set up is more standard, common failure modes are more quickly detected and proactively solved.

Therefore, in the column area, up to 50% of the 8% defect rate, or 4%, can be reduced by the implementation of the SPC control chart. From Figure 5, the top 4 most frequent failure modes, takes around 70% of all production defects, can be largely reduced by SPC implementation. An assumption is made that those 4 failure modes can be reduced by 70%. As a result, 49% of total defects were reduced, which is calculated by 70% times 70%. According to engineers in the shop floor, this is a conservative estimation of defect reduction. Notice that this 50% value is calculated from failure mode characteristic sheets for one specific part number. Because we do not have access to all of the characteristic sheets for the other column families, we assume 50% is the average value for the entire column area across different column families. As a result, we are confident that by application of control chart to the entire column area, there will be a 4% scrap rate annual reduction in total.

The future target of SPC control charting is not limited to just the column area, rather is but the entire machining center. From talking to the manufacturing engineer in the Waters machining group, the average scrap rate across different areas is more than 8%, which means the scrap rate reduction for the entire machining center is likely to be even higher than 4%.

One of the direct benefits of scrap rate reduction is annual quality loss savings, which will be discussed in Section 5.3. In addition, because the production quality is improved, Waters customer reputation and satisfaction will also be improved. Also, fewer defect parts being produced leads to less troubleshooting time during production, which results in a higher production rate. Last but not least, the control chart application, tools will be monitored and better used, and thus lower tooling cost will be incurred due to improper use of tools.

5.3 Potential Annual Savings

Different stakeholders hold different opinions towards the value added from the SPC control chart implementation project. For the operators, the ease of use and less setup time are most critical. While for the engineers, lower scrap rate and higher production rate are valuable improvement. But for the upper level management team, potential annual savings in dollars are of greatest value.

A brief calculation of potential annual savings is considered here. At the start of this thesis project, roughly 1.2 million dollars of annual production is lost due to scrap for the entire Waters global machining center. From the financial data of 2014 and 2015, around 40% of quality loss due to production scrap is from the column area.

The long term goal of this project is to scale up the SPC control chart implementation to the entire machining center. We assume that there is also 50% of failure modes of production defects that are related to tool change, tool wear, threading and initial setup, which can be monitored and eliminated by the new SPC control chart implementation.

6. Conclusion, Future Work and Recommendations

The deliverable requested of us at the beginning of the project was to develop an SPC methodology that is portable for Waters Corporation and that has been demonstrated by implementing it in the columns cell. The above deliverables have been achieved: a booklet containing an introduction to SPC, benefits of SPC, a training matrix, and standard operating procedures for implementation of SPC has been presented to the company.

This chapter discusses gage evaluation, real time inspection, and defect rate reduction due to application of control charts, potential annual savings, and future work for the company to ensure the longevity of SPC in the machining center. It gives an overall perspective of results achieved for the entire project. This chapter is written together with Zhang [7] and Zhu [8].

6.1 Gage Evaluation

By conducting the Gage R&R study, proper gages for the measurement of different dimensions on a column tube are identified. Evaluation of gage capabilities and root cause analysis for incapable gages have been conducted, with subsequent development of standardized procedures for inspection using gages, and improvement in the capabilities of key gages. Tolerances for certain dimensions are redesigned to ensure the validity of the SPC monitoring system without using the optical comparator. Thus, inspection protocols and measurement systems in the columns cell are made ready for SPC implementation.

6.2 Real Time Inspection

As noted in the problem statement section, one of the main purposes of this thesis project is to introduce a real time inspection tool that is easy to use, and provides accurate data to monitor the production process in the machining center. Experienced operators can apply the SPC methodology to better control the production quality and newly hired operators can also learn how to use this SPC methodology within a short period of time to achieve similar results as do experienced operators.

Real time inspection means that once a part is inspected, the corresponding data appears immediately in the control chart. With the control limits calculated from the initial setup, the operators can view the data points with respect to the control limits and specification limits on the screen. Western Electric rules [26] are integrated into the Prolink™ software, so that a warning when a data point indicates that a process has gone out of statistical control will automatically be shown on the screen. Thus, the operator does not have to judge the stability of the process by intuition. The operator's job becomes simpler by only having to enter the events and a possible reaction plan into the software to help build the root cause analysis database.

Besides ease of operation, SPC helps new hires to have a standardized quality control methodology that can be easily understood. Operator to operator variation is reduced, as every operator follows the same SOP for inspection of parts and the use of control charts, thus helping new hires make better decisions in the production process.

6.3 Defect Rate Reduction due to Application of Control Charts

In the previous year, the scrap rate for the columns cell was 8%. From the analysis of historical data on previous failure modes in the manufacturing of column tubes as shown in Figure 1:10, it can be demonstrated that the top failure modes account for 80% of scrap. The most frequent failure modes, as shown in Figure 1:10, are tool change, threads, setup and tool wear, and all of these can be reduced by our implementation of SPC. Scrap resulting from these failure modes can be reduced by approximately 60% or better by implementation of SPC. Therefore, the scrap rate in the columns cell is estimated to be reduced to 4%. Note that the 80% of scrap value is calculated from the failure mode characteristic sheets for one specific column tube. As all the other families of column tube share similar features, it is assumed that a similar percentage of the failure modes for the entire column cell can be reduced by implementing SPC. As a result, the scrap rate can be projected to reduce from 8% to 4% annually.

Waters' customer satisfaction is its highest priority. By reducing the scrap rate, customer orders can be met on time. This will increase customer loyalty to Waters Corporation, customer base expansion, help beat the market competition, and bring other benefits that will help the company's growth. Another benefit is reduction in tooling costs by not disposing of good tools and changing tools only when required.

6.4 Potential Annual Savings

Different stakeholders have different opinions towards the value added by implementing SPC. For the operators, ease of manufacturing and less setup time are helpful. While for the engineers, lower scrap rate and higher production rate are valuable improvements. For the upper management team, potential annual savings in dollars is the greatest value.

Using the same analysis for the entire machining center, a similar percentage of failure modes such as tool change, tool wear, threads and initial setup that now appear throughout the machining center can be reduced by implementing SPC.

6.5 Future Work and Recommendations

Given the time constraint, the SPC system was implemented for only several types of column tubes. A number of opportunities have been identified to improve the process further. This section describes recommendations for the company to consider in the future.

Firstly, a new database system should be established for better data management in the future. At present, the method of storing data is inefficient. Data is collected and stored in a file named with the part number of the column tube. Irrespective of which CNC machine performs the machining processes, no matter if the dimension is on the main side or the sub side of the column tube, the measurement results are stored in the same file in the same way, which means that data cannot be separated into different sets for further analysis. This is a major issue because different CNC machines have different inherent characteristics while producing the same column tubes. And in the CNC machine, the main side of the column tube is machined by different tools in different machining conditions compared to the sub side of the column tube. A new data structure will help manage the data better and deliver more valuable information in the future for process diagnosis and improvement.

A possible database structure is developed and shown in Figure 28. QCC is the central database for the whole SPC system. SAP is the internal system the company uses to share data.

All of the automatic gages feed their data into the central database and the data is integrated. Below the gage is the part structure. A gage can be used to measure column tubes, end fittings and other parts. First, the parts are divided on the basis of family. Parts in the same family share similar features and similar inspection protocols. Then there are different part numbers ("P/N"), and different sides machined by different CNC machines. In this way, all of the data can be separated in the future and then data management becomes an easier task.

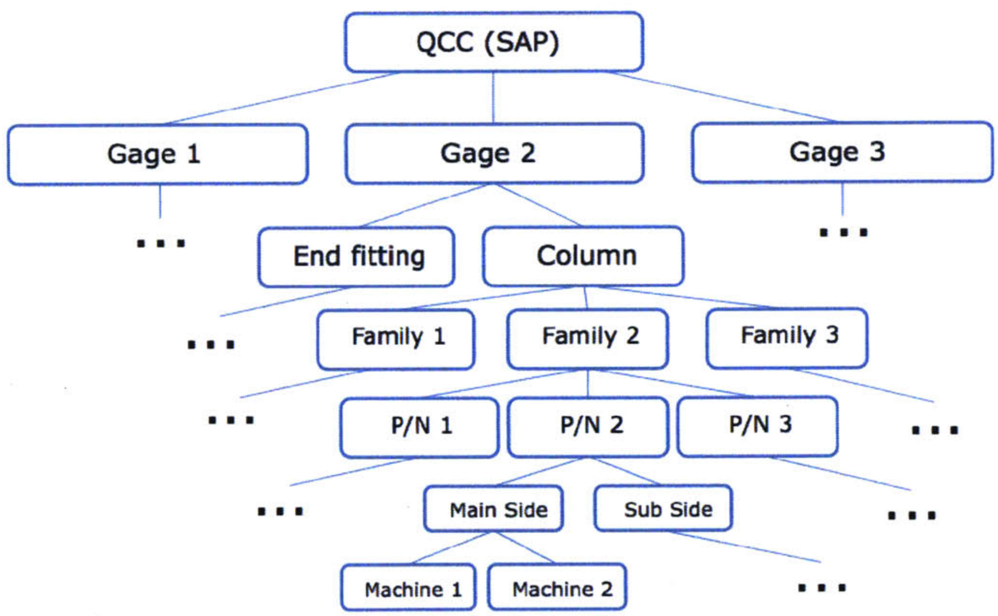


Figure 28: Recommended database structure.

Secondly, it is recommended to implement the SPC system across the entire machining center. As discussed in Section 6.4, there is a large potential for cost savings in the machining center. It is practical to implement SPC throughout the entire machining center with the help of the SPC methodology booklet that has been delivered to the company. With this portable SOP documentation, quality engineers will find it easier to incorporate the SPC culture in the different sections of the machining center.

Thirdly, a training program is recommended to help the operators understand the concept of SPC and be able to utilize it as a powerful tool to assist their daily production. A training program for the management level is helpful to foster a culture of better quality control.

Fourthly, data mining can provide potential opportunities for continuous process improvement. Once the system is set up, a number of data points can be collected every day. Beyond real time monitoring, this database can be used to identify failure modes and its frequencies. This will lead to a continuous improvement of the process. An example that illustrates this point is our analysis of data to identify that tool breakage was the main assignable cause for producing defective threads. Further analysis might include a tool life study in particular, to provide valuable insights to help indicate the proper time to change tools before they break.

Finally, regular maintenance is a vital part of the entire process. The SPC software needs to be maintained and updated regularly to provide real time control charts that will help the operators and the engineers. Data collected has to be regularly checked to ensure that data is not lost by other factors. If a new part or process is introduced, an updated inspection protocol should be developed for the continuous improvement of the manufacturing process.

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