Identifying Opportunities to Reduce Emergency Service Calls in Hematology Manufacturing using Statistical Methods

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Master of Science in Mechanical Engineering

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Abstract

The main goal of this project is to identify opportunities to improve the reliability of the DxH™ product line, an automated hematology instrument for analyzing patient blood samples. The product was developed by Beckman Coulter Diagnostics, a division of a Danaher operating company with principal manufacturing and support operations based near Miami, Florida.

A critical business metric used to reflect reliability is the Emergency Service Call (ESC) rate. An ESC for an instrument is defined as the number of unscheduled, on-site technician visits during the one year warranty period. Though Beckman Coulter already deploys an extremely robust quality control system, ESCs can still occur for a wide variety of other reasons resulting in an impact to reliability. Any tools that support the reduction of ESCs may help generate positive perceptions among customers since their instruments will have greater up-time.

This project entails an evaluation of a new initiative called "Reliability Statistical Process Control" (R-SPC). R-SPC is a form of manufacturing process control developed internally consisting of an electronic tool that collects raw instrument data during manufacturing. Unusual measurements are automatically sent to a cross functional team, which examines the potential trend in more detail. If an abnormal trend is identified, the examination could generate a lasting improvement in the manufacturing process.

Currently, the success of R-SPC is measured by the extent to which it reduces ESCs. Because an unusual measurement engenders further actions to investigate an instrument, it is desirable to show with empirical evidence that the measurement is linked to reliability. To assess whether particular measurements were systematically related to the ESC rate, relevant data were analyzed via the Pearson Chi Squared statistical test. The tests revealed that some of the variables now monitored do not appear to affect the ESC rate for the range of values studied. In contrast, several proposed "derived" parameters may serve as better indicators of an instrument's ESC rate. Moreover, the Chi Squared methodology described can be used to investigate the relationships between other variables and the ESC rate. The thesis concludes by offering several specific recommendations to help refine the R-SPC initiative.

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Glossary of Terms

Bulk Reagent – A consumable chemical used in sample processing.

Control Limits – Upper and lower fixed limits on a control chart that are determined by a statistical method. Typically, these limits are defined as +/- 3 sigma of the stable process; however, these can be made more stringent if extra attention is required.

Danaher Business System (DBS) – A set of frameworks that Danaher uses to operate and grow its businesses; continuous improvement and Kaizen are central components of DBS.

Daily Management – A meeting that occurs with a regular cadence to check the status of KPIs and assess what action should be taken and by whom.

DxH800 and DxH600 – Blood analyzers produced by Beckman Coulter, Inc. capable of high volume sample processing.

DxH Slide Maker Stainer – An instrument that automatically stains and deposits body fluid and blood samples onto slides for further analysis.

Emergency Service Call (ESC) - An unscheduled visit by a technician during a one year warranty period.

Emergency Service Call Rate – The normalized rate of ESCs per instrument per year. The metric is used to track reliability of various products, including the DxH800, DxH600, and Slide Maker Stainer.

Gemba Examination – The process of visiting the manufacturing floor to evaluate an observed symptom. If enough evidence of a trend is available, a formal investigation may be launched to drive towards a root cause.

Hematology – The branch of medicine that concerns the study of blood.

Investigation – A formal process of determining the root cause(s) of a problem. Usually the investigation is tagged with a Corrective Response (CR) number. The problem may manifest itself through visible symptoms.

Kaizen – The practice of continuous improvement. Kaizen is a core component of the DBS toolkit that is practiced through weeklong, dedicated activities for employees to address major organizational goals.

Key Performance Indicator (KPI) – A metric for tracking performance towards a business goal.

Operating Company (OpCo) – A company owned and operated by Danaher.

Numerical Characteristic – A raw measurement value recorded from the instrument. For example, a voltage reading.

Numerical Characteristic "*alpha*" – A numerical characteristic name used as a pseudonym for an actual characteristic ("beta" also used).

Parameter – A measurement derived from numerical characteristics. For example, power might be obtained by multiplying a sensor reading for current and a sensor measurement for voltage together.

Pearson Chi Squared Test – A statistical test that sorts events into mutually exclusive categories and makes a judgment about a given null hypothesis

Policy Deployment (PD) – A DBS tool that sets specific, breakthrough targets for the organization.

Reliability Statistical Process Control (R-SPC) - The name of the local initiative being considered in this thesis.

SPC Trigger – An event that occurs on a control chart that violates a set of static control limits.

SPC Trend – A series of events in time order that violate a predetermined set of rules. For example, eight points above the mean, yet still below the upper control limit. Such an event may be worth investigating further through a Gemba examination.

Specification Limits – Limits that are determined by engineering characterization. Though a product must meet the specification limits before being sent to the customer, the manufacturing process may or may not be capable of always producing a product within such limits without rework or other costly interventions.

Stable Process – A process where the desired output is achieved over a steady period of time. Data from a stable period can be used to calculate control limits.

Standard Work – A set of pre-defined steps for reliable repetition of a particular task.

"Voice of the Process"[1] – A phrase used to refer to the behavior of the process. Process output does not "listen" to the specification limits; instead a process must be tuned to create a product that falls within the desired specification limits.

1 Introduction

1.1 Problem Statement

The main goal of this project is to identify opportunities for improving the reliability of the DxH™ product line, an automated hematology instrument for analyzing patient blood samples. The product is manufactured by Beckman Coulter Diagnostics and is typically found in laboratories with medium and high patient sample volumes.

This project entails an evaluation of a new initiative called "Reliability Statistical Process Control" (R-SPC). Though Beckman Coulter has a well-developed and robust quality system, R-SPC is a form of *additional* manufacturing process control developed internally to boost the effectiveness of reliability improvement resources. R-SPC consists of an electronic tool launched in January 2015 that collects raw instrument data during the last steps of manufacturing prior to shipment to the customer and plots the data on X-bar and R control charts. Unusual measurements that violate a set of static upper and lower control limits are automatically sent to a cross functional team, which examines the outliers in more detail. Such examination may include visiting the affected instrument in manufacturing or cutting the data in a different manner to gain a better understanding of the trend. The team makes a determination about whether a trend has developed that might require further monitoring. The examination might also lead to a lasting improvement in the manufacturing process.

A critical business metric used to reflect reliability is the Emergency Service Call (ESC) rate. An ESC for an instrument is defined as the number of unscheduled, on-site technician visits during the one year warranty period under which the machine is covered. The aggregated ESCs for all instruments in the product line are called the "ESC rate," a metric that is tracked throughout the organization. High ESC rates are believed to contribute to negative perceptions among customers that can affect sales volumes. ESCs also impact warranty costs in terms of labor hours and part replacement. Even beyond the warranty period, service calls can affect customer perception and sales.

Currently, the success of R-SPC is measured by the extent to which it reduces ESCs. Because an unusual measurement engenders further actions to investigate an instrument, it is desirable to investigate with empirical evidence whether the measurement is linked to reliability. This project targeted which raw data should be considered, how static control limits should be calculated, and what standards should apply for initiating instrument examinations and subsequent investigations.

To assess whether particular measurements were systematically related to the ESC rate, a method was developed to apply the Pearson Chi Squared statistical test. The tests revealed that some of the variables now monitored do not appear be statistically consistent with the ESC rate for the range of values studied. In contrast, several unmonitored "derived" parameters hypothesized by the engineering team may serve as better indicators of an instrument's future ESC rate. These derived parameters consist of ratios or ranges of raw measurements. This result is not to say that the former variables are not useful, rather that other variables may be more "efficient" for identifying manufacturing trends that affect reliability. The Chi Squared methodology used here can be used to investigate the relationship between other variables and the ESC rate. As a result, this thesis offers several specific recommendations to reprioritize which measurements should be monitored and used to trigger action for the R-SPC team to ensure that resources are used most effectively.

1.2 Project Motivation and Voice of the Customer

The two major drivers of this project are (a) improvement of DxH instrument reliability in the field and (b) organizational learning that can eventually be transferred to other product lines. Management hypothesized that real time data collected from manufacturing can provide a clearer, faster approach to identifying trends on the DxH manufacturing line that impact instrument reliability. If such trends are detected, either with individual instruments or groups of instruments, examinations of the trends can be targeted to determine if countermeasures should be introduced. In addition, this data may lead to a broader appraisal of how to produce the instrument. Either way, the potential positive impact to the customer could be achieved through manufacturing process improvement.

In addition to directly improving DxH reliability, the project supported organizational learning by advancing the ability of employees to address business issues through rigorous statistical methods. Since R-SPC involved chartering a cross functional team that included manufacturing, product development, field service, and quality, these representatives could focus on reliability from their specific area of expertise. In addition, these representatives can bring the R-SPC method of thinking back to their teams. Eventually, the insights developed by the R-SPC team may benefit other product lines, which could encourage a more proactive approach to reliability improvements.

1.3 Thesis Overview

Sections 1, 2, and 3 provide an introduction to the problem and company background. Section 4 describes the current state of the reliability initiative and a literature review. Section 5 defines hypotheses about the problem and section 6 provides analysis of the results. Section 7 reviews several key case studies and section 8 summarizes the findings and provides room for future work. Section 9 provides references and section 10 is a detailed appendix.

2 Corporate Background

2.1 Danaher Corporation

Danaher is a large corporation consisting of several "growth platforms," a term defined by the organization to refer to a business area with at least $1 Billion in revenue and that typically maintains a number one or two market positioning.[2] Danaher was formed in 1983 by two brothers, Steven and Mitchell Rales, after their successful investments in manufacturing companies Master Shield, Inc. and Mohawk Rubber Company, and a real estate investment trust DMG, Inc. Their consolidated corporation was renamed "Danaher" after a favorite fly-fishing destination of the Rales brothers in western Montana. The Danaher River's name can be traced back to a Celtic root meaning "swift flowing."[3]

Soon after its founding, Danaher grew rapidly, joining the Fortune 500 in 1986 with revenues of $486 million.[2] Danaher frequently achieved stock price increases of 25% year over year due to a strategy of acquisitions and "buy to hold." Unlike private equity firms that seek to acquire a company and sell it within three to five years, Danaher typically purchases businesses that align well with its existing platforms and can be grown organically or with well-timed "bolt-on" acquisitions. This strategy helps generate strong cash flows for the parent company in the long term.

As of 2015, Danaher announced that it would split its business into two distinct companies with most industrial operating companies transitioning to "Fortive, Inc." and the high growth Environmental, Dental, and Life Science/Diagnostic operating companies remaining part of "Danaher, Inc."[4]

2.1.1 Portfolio of Companies

Today Danaher consists of five major growth platforms: Environmental, Test & Measurement, Dental, Life Sciences & Diagnostics, and Industrial Technologies[3]. Each platform contains a variety of relevant Operating Companies, referred to casually as "OpCos." Due to the vastly different product markets each OpCo participates in, each business is run independently by an entrepreneurially minded set of managers and technology experts. As a result of this distributed model, knowledge is shared across Danaher in the form of a generalized set of frameworks called Danaher Business System Tools, or DBS Tools. Despite operating in different markets, every OpCo is expected to adopt the methodologies and mindset of DBS, particularly the culture of continuous improvement. Figure 1 provides a summary of Danaher's major operating companies and approximate revenues in 2015.

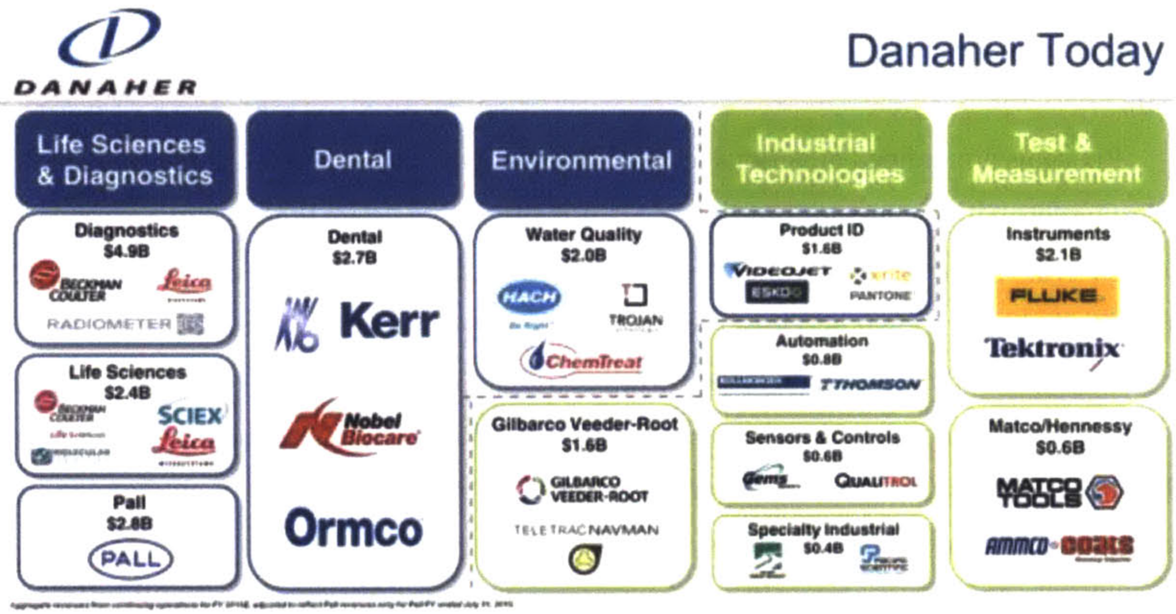

Figure 1: Danaher Portfolio of Companies showing future split of Danaher (left, blue) and Fortive (right, green)[5]

2.1.2 Danaher Business System (DBS) Tools

In the 1980s, Danaher underwent a period of rapid growth that included the acquisition of Jacob Vehicles Systems (JVS or "Jake Brake"), a manufacturer of air brakes for the trucking industry. JVS had been developing competencies in operational excellence through studying the Toyota Production System. Danaher decided to adopt JVS methodologies throughout the corporation and invest in bolstering their continuous improvement competencies by encouraging its OpCos to use the techniques and develop their own improvements[2]. Eventually, the methods were codified into a set of standard, though evolving, tools called the Danaher Business System, or DBS. DBS tools are now deployed across the organization and used as the method for vastly different OpCos to share knowledge about best practices. It is expected that every OpCo, new and old, adopt and practice DBS. Several key DBS tools relevant to this project are discussed below.

2.1.2.1 Policy Deployment

Policy Deployment (PD) is the set of goals that the business wants to achieve but does not yet know how to do so. These goals are typically "stretch" in nature but still plausible given the environment. Since PD goals are set rather aggressively, they encourage original breakthrough thinking. A hypothetical example may be to increase revenues by 15%. Under conventional goal setting methods, revenue growth targets may only be set to 5%. By setting the target much higher, the intent is to motivate employees to find innovative ways to meet the goal. Even if 15% cannot be met, 9% performance would be a success and much preferred to the alternate goal of 5% revenue growth.

PD goals are defined at various levels of generality with "level one" (L1) being the highest, broadest targets with the greatest importance. Normally, L1 goals are broken into several "level two" (L2) goals to create more manageable tasks that can be assigned to specific employees. The goals continue to be broken down into lower levels until the targets are accessible and understandable. Every PD goal usually has several responsible individuals and some of these responsibilities might be overlapping based on function. For example, the L1 PD goal to reduce the ESC rate by 50% for the DxH800, DxH600, and DxH SMS products is shared by Manufacturing, Field Service, and Product Development among others.

2.1.2.2 Key Performance Indicators (KPIs)

Key Performance Indicators are quantifiable metrics that help managers and employees understand and evaluate the state of the business. KPIs vary depending on area and function and are designed to flow from a Policy Deployment goal. For instance, monthly revenue may be a KPI for the Sales department, on-time delivery percentage might be a KPI for the Manufacturing group, and Service Effectiveness (the percentage of time a technician fixes an issue on the first visit) may be a KPI for the Field Service group. KPIs help sustain a desired state of the business and can also be used to help progress towards a PD goal. Since no single KPI can perfectly communicate the state of the business, it is common practice to use multiple KPIs. Overall, the goal is to choose KPIs that accurately represent business health while providing the minimum amount of information for sound decision making. It is important that the set of KPIs monitored is not overwhelming and that they are frequently reevaluated for relevance to PD goals.

In the case of R-SPC, the ESC rate is a critical KPI. However, to make the top level goal of ESC reduction more tangible, other "secondary KPIs" are used to help the team understand what should be a priority on a daily basis. For instance, the number of monitored numerical characteristics tracked by the team must exceed 20, but not be greater than 30. This ensures that only a reasonable number of R-SPC triggers reach the team and the workload remains manageable in a given time.

2.1.2.3 Daily Management

Daily Management (DM) is the practice of regularly reviewing KPIs to determine if the business or project is "winning or losing." DM does not need to take place every day, but must be more than once per month. At every DM meeting, a team of project stakeholders meet in front of a visual management board that tracks the appropriate KPIs. Each KPI is compared to its desired level; if the KPI exceeds the target, it is highlighted in green; otherwise, it is highlighted in red. Any item in red will be discussed by the team to understand what is being done to address the missed target and what roadblocks stand in the way. For example, if the target on time delivery (OTD) for product X is 95% every Friday, and last week's OTD was 90%, the team will attempt to identify the cause of the miss. If the cause is not immediately apparent, the relevant stakeholder will be assigned to investigate using a DBS tool called the "Problem Solving Process" (PSP). PSP uses the continuous improvement method called the "five whys" which seeks to continue asking "why" something is the way it is until the root cause is found. When appropriate root cause(s) are identified, countermeasures can be devised that specifically address the root cause(s). The implementation progress of such countermeasures can then be tracked at the next DM.

2.1.2.4 Kaizen

Danaher incorporates the Japanese methodology called "Kaizen" into its DBS tools. Kaizen roughly translated into English from Japanese means, "change for the better."[6] The term often refers to the set of methodologies used to practice continuous improvement. Kaizen originally started out as a manufacturing oriented tool, however, it is extremely applicable to other business areas such as sales, marketing, and transactional processes. At Beckman Coulter, "Kaizen is our way of life" is clearly displayed around the workplace. The R-SPC initiative originated from a Kaizen event.

At Danaher, Kaizen is implemented through weeklong events that have a well-defined team and goal. Prior to the event, a team lead constructs a charter to identify the problem, builds a team, and sets KPIs which will be used to measure success. During the Kaizen event itself, which lasts one week, all team members stop their normal work activities to focus exclusively on the Kaizen goal. After any Kaizen event, any gains must be sustained in the long run using a robust sustainment program that employs the same KPIs and tracks progress for at least 90 days. Sustainment is usually the most challenging part of any Kaizen since it is sometimes easier to revert back to old methods.

2.1.2.5 *Distribution of Work*

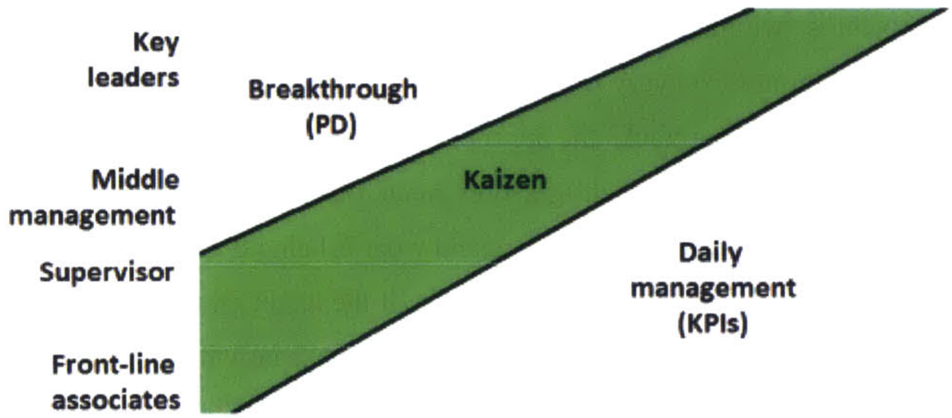

Figure 2: Distribution of Policy Deployment, Key Performance Indicators, and Kaizen (from DBS training resources)

Figure 2 shows the breakdown of how the organization should spend its time. The amount of time spent performing daily management, Kaizen, and developing breakthrough policy deployment goals will naturally vary with the level of responsibility. Everyone is still responsible for engaging with Kaizen and Daily management activities. However, as employees gain increasing levels of responsibility, they focus more attention on setting breakthrough PD goals.

2.1.2.6 *Danaher Reliability System – 6 Pillars*

The Danaher Reliability System is a critical DBS tool that helps ensure that every Danaher product reaches the customer with high quality and reliability. Designing, building, and shipping reliable products are important to both the customer and Danaher. The customer benefits by increased uptime of their product between service visits which results in greater productivity. Danaher benefits by fostering positive brand perception that generates more sales through customer referral and loyalty. Similarly, savings in warranty costs and service capacity allow for greater investment in new products and services that offer value to customers and shareholders alike.

The DRS model focuses on six pillars whose core consists of Design for Reliability, Supplier Quality Management, Manufacturing Process Control, and Customer Service and Support. The last two concepts are a method of Customer Defect Tracking and Resolution and Leadership Focus on Reliability. The relationship between these six pillars is shown in Figure 3.

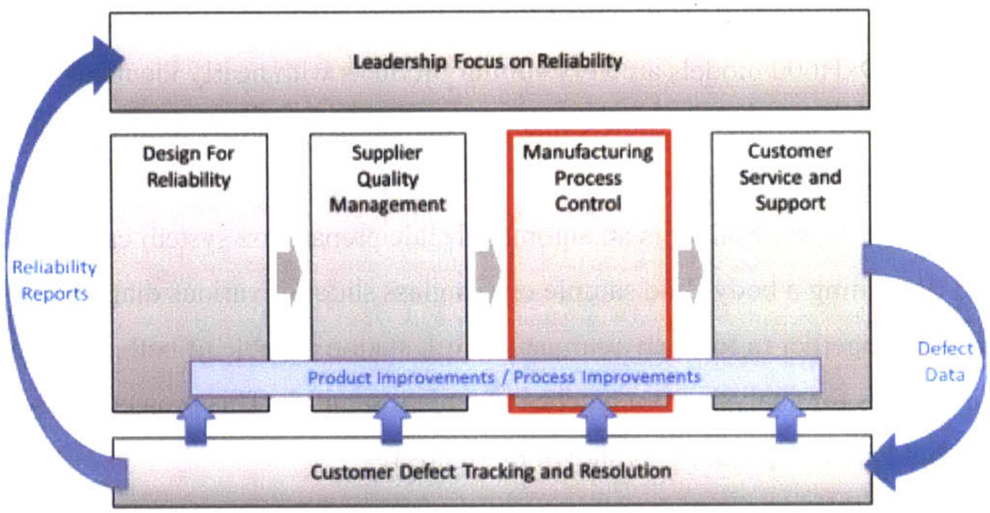

Figure 3: Danaher Reliability System (DRS) demonstrating conceptual relationship between the 6 pillars. This project focuses on the Manufacturing Process Control element of DRS.

R-SPC attempts to improve reliability through the Manufacturing Process Control Pillar of the DRS. The initiative is driven from manufacturing and focuses on what can be learned about reliability from the production process.

2.2 Beckman Coulter Diagnostics, Kendall, FL

2.2.1 Hematology and the Coulter Principle

The Coulter Principle was discovered in the 1940s as a method "for counting and sizing particles using impedance measurements".[7] The first successful, accurate blood cell counting device was invented in 1947 and commercialized in 1953 by Wallace Coulter who used his recently discovered "Coulter Principle" in the product[8]. Over the decades, Coulter Corporation continued to improve its technology and released a wide variety of innovative diagnostics products in the Hematology space[9]. Originally part of the Coulter Corporation, the Hematology group became part of Beckman Coulter Diagnostics in 1997 after Beckman Diagnostics purchased Coulter Corporation to form Beckman Coulter, Inc.[10] In 2011, Danaher purchased Beckman Coulter.[11]

2.2.2 DxH Product Line

The DxH product line is the latest in a long line of cutting edge Hematology analyzers that perform diagnostics on a sample of patient's blood. Though the fundamental Coulter principal is still used, today's machines are far more sophisticated than the original Coulter Counter. The DxH product line consists of several instruments including the DxH800, DxH600 and the DxH Slide

Maker Stainer. The product line is designed for medium to high volume laboratory environments. The DxH800 and DxH600 models are very similar products with nearly identical form factors; however, the DxH800 has slightly more capability including the ability to measure immature red blood cells known as reticulocytes.

The DxH Slide Maker Stainer is an automated slide preparation system capable of extracting, staining, and depositing a body fluid sample onto a glass slide for various diagnostics. The systems can be connected together to form an automated work station capable of both performing diagnostics and preparing slides for analysis from batches of patient samples. This project focuses primarily on the DxH800 and DxH600 products as shown in Figure 4.

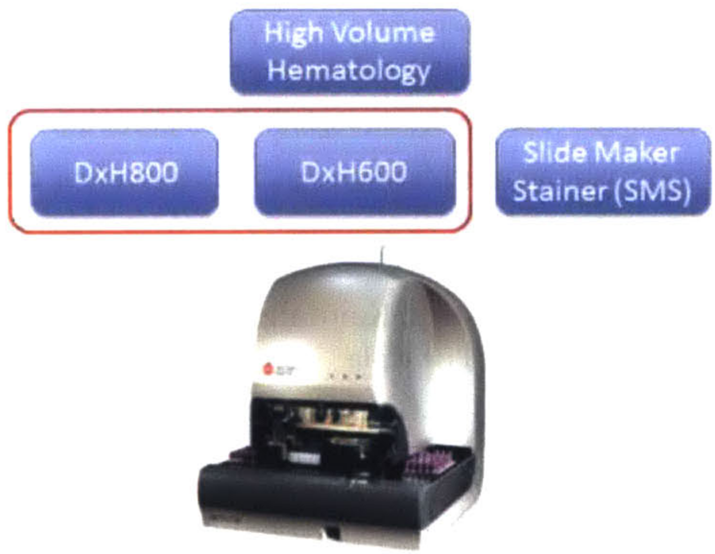

Figure 4: UniCel DxH800 Blood Analyzer; Beckman Coulter's flagship high volume diagnostics product for Hematology

2.3 Controls and Calibrators

To operate DxH products requires employing various consumable materials to calibrate the instrument and ensure consistent performance. Descriptions of several materials, including blood analogues, latron, and bulk reagents, are described below.

2.3.1 Blood analogues

One of the more important consumables used in the DxH product line is blood analogues. Blood analogues are manufactured from animal products based on a proprietary process. Typically, three products, called "levels," are produced to mimic the Complete Blood Count (CBC) of an individual in various health states. Level one consists of low CBCs, level two consists of normal CBCs, and level three consists of abnormally high CBCs. Using these three levels, a technician can calibrate the instrument to recognize normal and abnormal blood.

2.3.2 Latron

Latron is a suspension of synthetic particles of a certain concentration. The particles are manufactured to be a certain size with a known variability around the mean. Latron is used during instrument manufacturing and in the field to provide another, non-biologic source of instrument verification.

2.3.3 Bulk Reagents

Several bulk reagents are used in the system to assist with sample processing. These include various diluents, stains, and cleaners. These products are produced in facilities around the world according to a product specification.

2.3.4 Hematology Quality Control and Assay

Every lot of blood analogues is shipped with an "Assay Sheet" that lists values for relevant parameters, including CBC count. These values may vary from lot to lot due to normal process variation; however, they are always released within specification using a set of well-maintained instruments from the Hematology Quality Control (HQC) group. As a result, these instruments are the standard bearers for all instruments in the field. Quality is always essential part of the manufacturing process for all consumable materials used in the DxH product line.

3 DxH Reliability Initiative in Manufacturing

3.1 Emergency Service Call (ESC) as a Key Performance Indicator

An ESC is defined as an unscheduled service visit to a customer site for any reason during a one-year warranty period. Overall, the ESCs are added together and normalized per unit time to obtain an ESC rate. For hematology analyzers, the KPI for ESC rate reported to top management consists of a weighted yearly average of three products: DxH800, DxH600, and the Slide Maker Stainer (SMS). In 2015, the PD goal was to reduce the number of ESCs by 50%, of which a certain portion was to be obtained through manufacturing improvements from R-SPC monitoring efforts.

For the DxH product family, a large portion of the installed base consists of DxH800 and DxH600, which are functionally very similar. The remainder of the installed base consists of SMS devices. Management has hypothesized that ESCs are related to customer perception of the product line which can impact sales targets. ESCs are considered defects in the Danaher Reliability System, even if quality is not directly affected.

3.2 Reliability Statistical Process Control (R-SPC) Monitoring Tool

As part of continual improvement, Beckman Coulter conducted a Kaizen in 2015 to setup Statistical Process Control on the manufacturing line for the DxH800 and DxH600. The goal was to collect data that could be used to monitor the line in real time to (a) detect individual instruments that deviate significantly from normal and (b) identify trends that may stem from the manufacturing process and affect groups of instruments. Figure 5 shows at a high level the flow of information from manufacturing to a cross functional team that is tasked with examining trends.

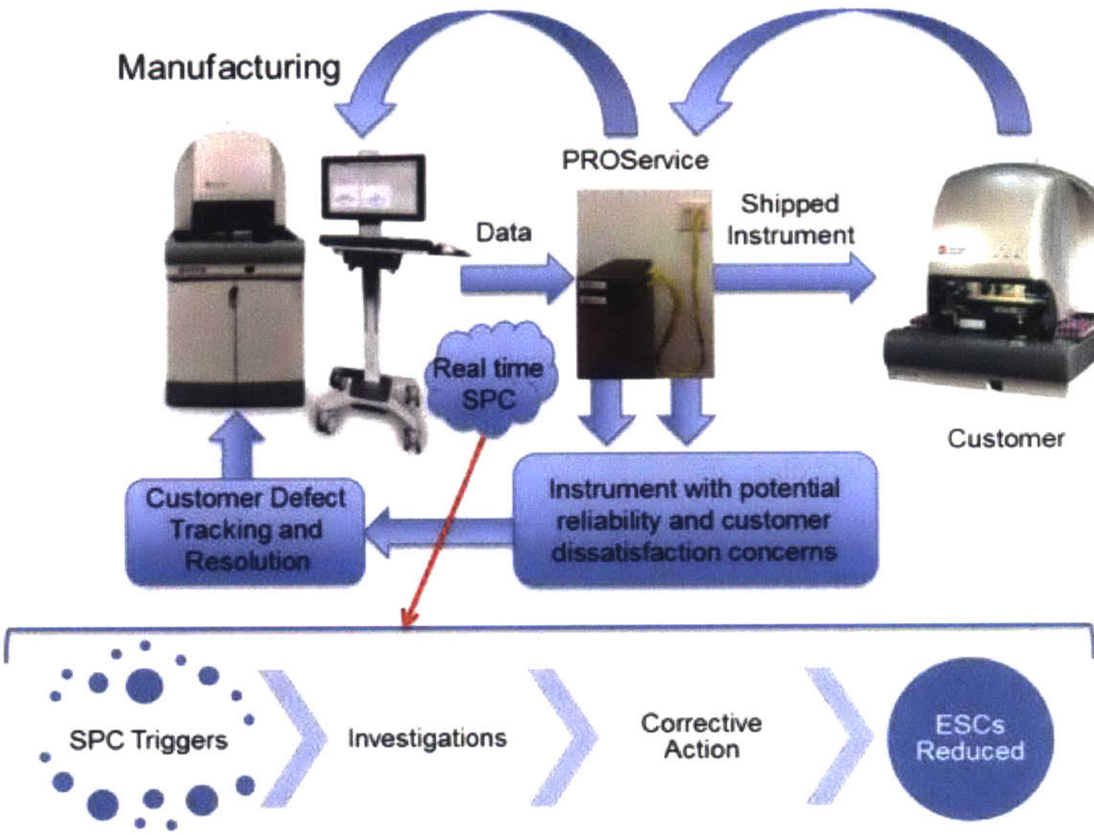

Figure 5: Reliability Statistical Process Control (R-SPC) configuration in DxH800 and DxH600 manufacturing showing the flow of data from ProService to a Real Time SPC engine

3.3 Cross Functional Reliability Team

The R-SPC reliability team consists of a cross functional group from manufacturing, field service, product development and quality. The effort is driven from manufacturing with the goal to contribute to ESCs reduction for DxH800 and DxH600 instruments. The cross functional nature of the team is critical for problem solving and ensuring that trends are identified and addressed in a timely manner.

4 Statistical Methods

4.1 SPC tools

Statistical Process Control is an extremely effective method of ensuring quality products are produced in a manufacturing environment. Several important tools (sometimes called the "Magnificent Seven"[12]) include:

1. Histogram or stem-and-leaf plot
2. Check sheet
3. Pareto chart
4. Cause-and-effect diagram
5. Defect concentration diagram
6. Scatter diagram
7. **Control Chart**

Though DBS includes examples of each of these methods, this thesis focuses primarily on the Control chart and its applications for reliability improvement. In particular, R-SPC makes heavy use of X-bar and R control charts to plot numerical characteristics. In addition to the control chart, the Chi Squared method is used extensively to examine the effectiveness of using specific characteristics in the R-SPC initiative.

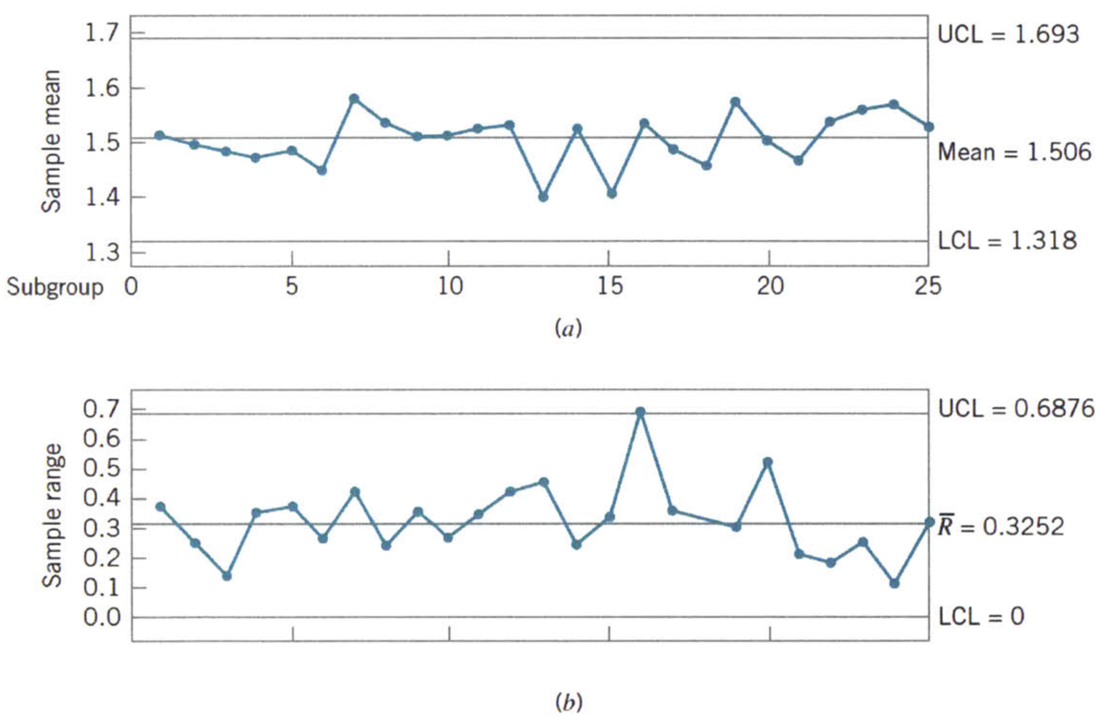

Figure 6: Generic X-bar and R control chart[12]

4.2 Control Charts

The R-SPC initiative uses X bar and R control charts to plot important numerical characteristics over time in manufacturing. Figure 6 shows a standard X-bar and R control chart. Graph (a) is the sample mean of the subgroup and graph (b) is the range of the subgroup. The concept of this charting mechanism is used widely in the R-SPC initiative. Figure 7 shows an example of a control chart for a numerical characteristic of interest.

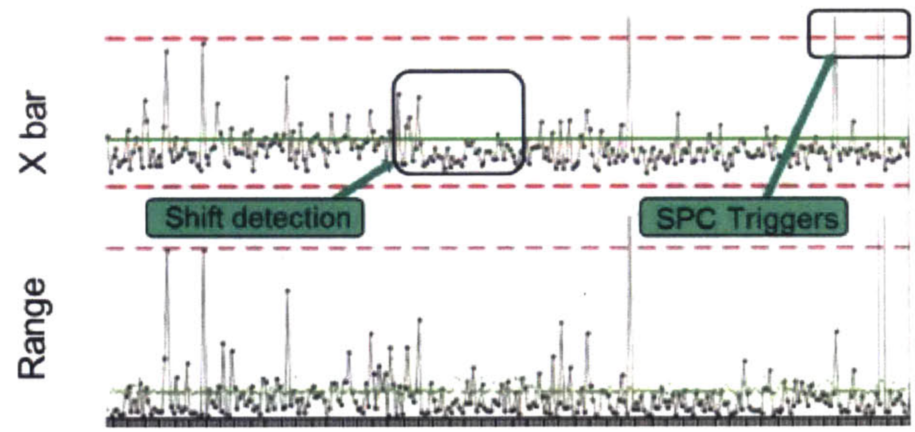

Figure 7: Example of an X-bar and Range control chart for a numerical characteristic showing where shifts and outlier points can be detected

The goal is to identify instances when a particular numerical characteristic moves out of bounds so that further examination can be conducted by the R-SPC team. With this chart, the team can examine when the numerical characteristic exhibits a noticeable shift and/or when the numerical characteristic exceeds the set of static control limits. Either case provides a reason to go to Gemba and examine the manufacturing floor in more detail.

4.2.1 Identifying individual instrument trends

With statistical process control it is possible to identify potential trends with individual instruments through use of a control chart. Each control chart is a time series plot of a numerical characteristic that is deemed to be important for reliability using engineering judgment. For instance, Figure 7 demonstrates an example of a measurement violating a set of static control limits on an instrument during final test in manufacturing. The result is a notification sent to a manufacturing team member for further investigation.

4.2.2 Identifying trends in groups of instruments

In addition to identifying individual outliers that violate the static control limits, when multiple points are outside of the designated control limits, it might be possible to identify a trend with a group of instruments. For example, Figure 7 shows an example of a shift of several points in a row. In such cases, an investigator must take a closer look at the manufacturing process to see what might be causing the sudden change in behavior. In general, this should be the goal of statistical process control: find trends in the data, go to Gemba to determine why the trend appeared and, if necessary, perform a root cause examination to develop appropriate countermeasures.

4.2.3 Control Chart Limitations

In general, the control chart provides a method to tell the user that something has changed and that it deserves a second look. R-SPC makes this process very straightforward because emails are sent to the team in real time. However, examining the manufacturing line is only useful if the numerical characteristic in question is "worth" examining. Statistical process control can tell us where to look for problems, but it cannot tell us why we are looking at the instrument and what the problem is (if any). To ensure that the R-SPC team is using the most appropriate data sources, another test, known as Chi Squared, lends itself well to building evidence for using certain numerical characteristics by combining R-SPC measurements with field data.

4.3 Hypothesis Testing and the Chi Squared Test

Statistical hypothesis testing is a common methodology for determining whether a given null hypothesis is consistent with the data collected. A null hypothesis can be generated from nearly anywhere, as long as it is not biased from external sources. For the purposes of this thesis, we are interested in whether the R-SPC initiative is effective in reducing ESCs. Determining outright whether any initiative is effective is a challenging task; however, statistics can help us by providing meaningful evidence in one direction or another.

A particularly good test suited for the task of evaluating the R-SPC initiative is the Chi Squared Test. To understand how the test works, it is useful to consider a classical example about uniform birthdays. In this example, the null hypothesis (H_0) is that every month in the year has the same number of birthdays as any other month in the full population. If this is true, we would expect that for a sample of N individuals, that N/12 people would have birthdays in January, N/12 people would have birthday in February and so on[13]. With the null hypothesis stated, it becomes possible to go out into the field and collect some data. For example, if 120 people are asked about their birthday, it is possible to determine the number of people whose birthday falls into each month. With 120 people surveyed, we would expect that 10 people fall into each category. Of course, due to random variability with a sample, we may find that some of the categories do not have exactly 10 members. So how do we know if the sample we drew looks "close enough" to uniform to not feel compelled to reject the null hypothesis that birthdays are uniform? The chi-squared test provides a method in the form of a discrepancy score that reflects the deviations between expected and actual outcomes according to the formula[13]:

$$\chi^2 = \sum_{i=1}^{n} \frac{(O_i - E_i)^2}{E_i} \qquad (4.3.1)$$

After computing the discrepancy score for each month and summing them up, the result is compared to a threshold criterion. If the test statistic is greater than the threshold, the null hypothesis is rejected, otherwise it is accepted. For example, suppose the survey looked as follows:

Month	Count	Expected	Distance from expected	Discrepancy Score
Jan	10	10	0	0
Feb	8	10	-2	0.4
Mar	12	10	2	0.4
Apr	11	10	1	0.1
May	10	10	0	0
Jun	10	10	0	0
Jul	7	10	-3	0.9
Aug	11	10	1	0.1
Sep	12	10	2	0.4
Oct	10	10	0	0
Nov	9	10	-1	0.1
Dec	10	10	0	0
Total ->	120		Chi Square Statistic ->	2.4

Figure 8: Hypothetical example of data collected to consider the uniform birthday hypothesis

For each month, the discrepancy score is calculated. By summing each partial score, the overall test statistic of 2.4 arises. But what does 2.4 mean and what threshold should it be compared to? The threshold value for the test is governed by the confidence level (normally 95%) and a quantity related to some specific details about the test, such as the number of categories. This other quantity is known as the, "Degrees of Freedom" (DOF). The DOF value is calculated using the following formula:

$$DOF = \varphi = m - m_p - Q \qquad (4.3.2)$$

where m is the number of categories, m_p is the number of "puppet" categories, and Q is the number of instances where the test required "peeking" at the data. The number of categories in the example is 12 (there are 12 months). The number of puppet categories is the maximum number of categories that can be omitted while still being able to compute the number of events in each. For example, if there are 120 people and it is known how many events are in each of 11 categories, the number of events in the last category can be found. Thus, the number of puppet categories is one. In this case, we do not "peek" at the data to gain a better estimate of the expected value, so Q = 0. (Note: Peeking would only be performed in circumstances where a better understanding of the expected value is necessary. The topic is not addressed further in this thesis).

Thus, there are 11 degrees of freedom. Using a lookup table, the threshold value for DOF = 11 and a confidence level of 95% is 19.7[14]. As a result, the test statistic of 2.4 can be compared to 19.7. Since 2.4 < 19.7, we fail to reject the null hypothesis and conclude that the data is consistent with the hypothesis that birthdays are uniform.

In the case of R-SPC, control charts are telling us where to look. When instruments are examined, resources are hopefully being spent on areas of the manufacturing process that affects reliability the most in terms of ESCs. For instance, if the value of a numerical characteristic is too high (violating a control limit), we might suspect the instrument may trend in a direction that, if left unchecked, could reach the field and fail prematurely. This idea is explored in subsequent sections.

5 Problem Hypotheses

Proactive activities are more desirable than reactive ones. For example, it is better to detect a defect during manufacturing than have a customer experience a shutdown later in the field. Not only does this prevent the customer from experiencing potential problems, but it also reduces the cost associated with resolving the issue later when the instrument is far away, good information is difficult to obtain, and resources spent on accessing the instrument are significant. R-SPC represents a worthwhile and noble effort to not only deliver standard high quality, but also high reliability. The following are hypotheses that will be analyzed with examples in section 6.

5.1 Actively monitored raw numerical characteristics measured during instrument manufacturing are indicative of future DxH800 and DxH600 Emergency Service Call Rates.

The R-SPC initiative relies on measuring and monitoring a variety of instrument numerical characteristics from nearly finished DxH instruments in manufacturing. To the R-SPC team, any data point that exceeds predefined control limits are cause for concern and prompt a Gemba visit. In many instances, however, the observed data point that exceeded the control limit does not similarly violate a specification limit. Thus, to the manufacturing operators, there is no reason to perform a deeper examination. Also, when a further examination is conducted, frequently no issues are found with the instrument.

This suggests that it is worth evaluating whether or not monitoring such numerical characteristics is worthwhile. In other words, do the data from certain numerical characteristics suggest that there is a relationship between its numerical value and the number of times the instrument is subsequently serviced in the field (ESCs)? Answering this question could help redirect team resources to other more important numerical characteristics that have greater influence.

One possible null hypothesis (H_0) that can be tested for a numerical characteristic is: the number of field failures is uniform for every instrument whether the numerical characteristic is "low," "medium," or "high." If we can find data to suggest otherwise (H_a), then we have evidence that the parameter may be related to the ESC rate and thus deserves extra scrutiny.

5.2 Design changes can be detected and sustained using R-SPC data

Another major hypothesis concerns the ability to detect and sustain design changes. When a potential reliability problem is identified, resources are spent to design a solution and deploy it on the manufacturing line. Such changes could be software, hardware, or process related and be sourced from a number of contributing departments through a rigorous design change process. In some instances, it is possible to detect changes in the product using R-SPC and through a later review of the ESC rate. For instance, it may be possible to track a numerical characteristic, or derive a parameter from several numerical characteristics to track instrument performance. Once such an indicator is identified, it may become worthwhile to track this indicator over time and respond to any trends that come to light.

5.3 Reliability SPC Initiative workload benefits from methodology changes

5.3.1 Reduced quantity of tracked numerical characteristics improves investigations

Another hypothesis is that when the number of numerical characteristics or parameters being tracked is reduced, the workload of the investigators will similarly decrease assuming that the rate of SPC triggers remains the same. This is sometimes called "focusing on the critical few."

5.3.2 Modified standard work impacts investigation effectiveness

Standard work is extremely important to effective execution of the R-SPC initiative. Without a set of logical, documented steps, the team will not perform according to its full potential. Introducing standard work to daily management, instrument troubleshooting, and calculating control limits, among others, will benefit the R-SPC process.

6 Analysis and Results

6.1 Applying the Chi Squared Test to Chosen Numerical Characteristics

Evaluating the importance of a particular monitored numerical characteristic from the DxH requires first making a list of probable characteristic candidates using expert input. A statistical test can then be conducted to compare the level of the numerical characteristic at manufacturing to the number of ESCs the instruments received in the field. In some cases, it is necessary to be more specific since an ESC can occur for many reasons and be due to a particular subsystem in the instrument (see appendix 10.1). Ideally, in these circumstances each numerical characteristic would be classified by the type of failure mode that engineering intuition would suggest. However, if this is not available, the overall number of ESCs can be used.

As in the birthday example, categories must be chosen for the Chi Squared test. One reasonable set of categories might be instruments with a "low," "medium," or "high" value of a particular numerical characteristic. For these three categories, we simply split the data into thirds. If the X-bar value of the characteristic for a particular instrument is in the lower 33%, it is considered "low" (L). If it is in the middle 33%, then it is "medium" (M), etc. So far this means we have three categories (low, medium, and high). However, we must still relate this classification to "ESC performance" of the instrument once it is in the field for a reasonable period, such as 90 days. We might therefore increase the number of categories to nine by labeling instruments by both numerical characteristic level and performance in the field, as measured by whether the instruments had 0, 1, or 2+ ESCs during the 90 period. These three performance levels seem reasonable because instruments with no problems would have zero ESC, while especially problematic instruments would be expected to have two or more ESCs. Thus, the nine categories are: L-0, M-0, H-0, L-1, M-1, H-1, L-2+, M-2+, and H-2+.

If the numerical characteristic under study is unrelated to performance, we would expect that instruments with 0 service calls will be about equally spread among low, medium, and high ranges of the numerical characteristic. The same would also be true for instruments with 1 service call within 90 days, and for instruments with 2 or more service calls within 90 days. The Pearson Chi Squared test (described in section 4.3) can be used to determine if the difference between the number of ESCs in a 90 day period and the numerical characteristic level is significant enough to conclude that the relationship did not just occur due to chance alone.

The basic procedure for sorting the data is as follows:

1. For each instrument, count the number of service calls received within 90 days after shipment (this period is hypothesized to be the window at which the manufacturing process most impacts reliability in the field).
2. For each instrument, identify if the value of the target numerical characteristic was in the top 33%, middle 33% or lowest 33% of the dataset.
3. Tally the number of instruments in each category and assemble a 3x3 table representing the nine different states.
4. Conduct a Pearson Chi Squared test using JMP to obtain a test statistic, threshold, and p-value. If the p-value is less than .05 (95% confident), then it is likely that the differences between categories were not due to chance alone and that the numerical characteristic may be an indicator of instrument reliability as measured by ESC.

The following is an example of a Chi Squared Test performed for an example numerical characteristic *alpha* for a recent four-month manufacturing period:

Level/Cat	0	1	2+	Total
H	71	29	23	123
L	77	24	18	119
M	76	18	25	119
Total	224	71	66	361

Figure 9: Numerical count and percentage of total for high, low, and medium values of *alpha* by instruments with 0, 1, or 2+ failures within 90 days of shipment for a recent four-month period

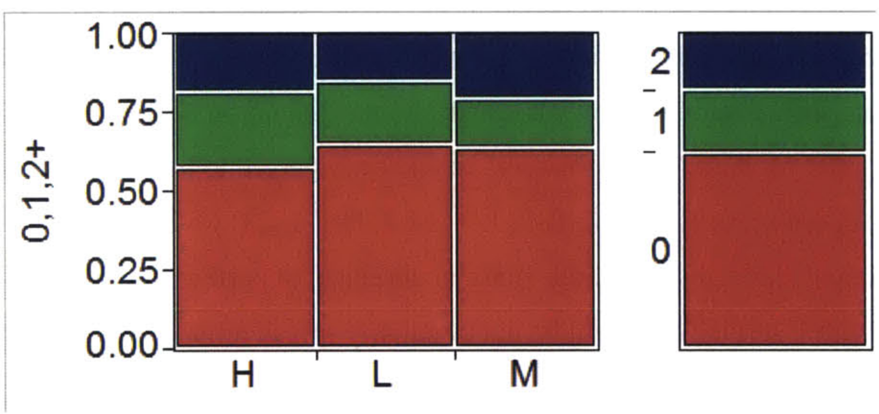

Figure 10: Visual breakdown between high, low, and medium values of *alpha* by instruments with 0, 1, or 2+ failures within 90 days of shipment for instruments manufactured during a four-month period

It would be expected that the number of instruments having zero service calls in 90 days is the same regardless of whether the value of *alpha* was in the top 33% (H), low 33% (L) or middle 33% (M). The same is true for instruments having one service call, or two or more service calls. In this case, the number of instruments having zero service calls appear relatively split between the categories with values of 71, 77, and 76 respectively. The same is true of instruments with one service call (29, 24, and 18) and instruments with two or more service calls (23, 18, and 25).

Now that the categories have been determined, it is appropriate to define the pass/fail threshold for the test. It is conventional to use a 95% confidence level and we will use it here. However, with these nine categories, what would be the degrees of freedom? Referring to the discussion in section 4.3, DOF = $m - m_p - Q$. In this case there are clearly nine categories, so m is nine. But what about the number of puppet categories, m_p? In other words, how many categories must we know to compute the remaining categories assuming the total number in each is known? One such permutation is shown in the table below:

Level/Category	0	1	2+	Total
L	Known	Compute (3)	Compute (4)	Known
M	Known	Known	Compute (5)	Known
H	Compute (1)	Compute (2)	Known	Known
Total	Known	Known	Known	TOTAL

Figure 11: A minimum of four categories must be known in order to compute the other five categories. Thus, the number of puppets categories is five

Since we know the totals for each row and column, the number of puppet categories is five. Also, we do not peek at the data, so Q = 0. As a result, DOF = 9 - 5 - 0 = 4 degrees of freedom. Thus, the discrepancy score for this Chi Squared test statistic must be compared to a threshold value computed using 95% and 4 DOF. This value is 9.49[14]. Running the Chi Squared test, we obtain a discrepancy score of 3.932. Comparing this to 9.49, we find that the test statistic is well below the threshold value.

N (instruments)	DOF	Test Statistic (Discrepancy score)	Threshold (95% confidence, DOF = 4)	P-value
361	4	3.932	9.49	0.42

Figure 12: Summary of statistical results for Numerical Characteristic *alpha* showing a p-value of .42; there is not enough evidence to reject the null hypothesis

Thus, we conclude that the data is consistent with the null hypothesis and *alpha* may not be as effective in informing the team about the ESC rate as other numerical characteristics. However, slightly more information can be determined than just a pass/fail answer. There also is the matter of p-value which will tell us something more about this result.

In this case, we find the p-value to be .42. What exactly does this mean? Essentially, this is the chance of finding an outcome *at least as hostile* to H_0 as to H_a. In other words, there is a 42% chance of finding an outcome that is worse for the null hypothesis: Low, Medium, and High categories should have the same number of instruments within each subgroup of 0, 1, or 2+ ESCs. This means that we are not too sure that the null hypothesis is false, and thus we assume it to be true until further information comes to light.

6.2 Assessing whether design changes can be detected by R-SPC

When a design change is implemented on the manufacturing floor, it is desirable to see whether any improvements can be measured in terms of ESC. One such example of an improvement is the release of a hardware change for the vacuum supply in the DxH800 and DxH600 instruments. For certain failure modes, the measured value of pressure is important to keep within a particular specified range. In some instances, the measured value fluctuated widely inside the specification range during the Daily Checks cycle.

R-SPC already measures a wide variety of numerical characteristics, including three pressure measurements. Independently, these pressure measurements may not be of interest, but when considered together, the additional information may be useful. When the range of these pressure measurements is calculated (parameter *beta*) and plotted in time order, a drastic difference can be observed as shown in Figure 13.

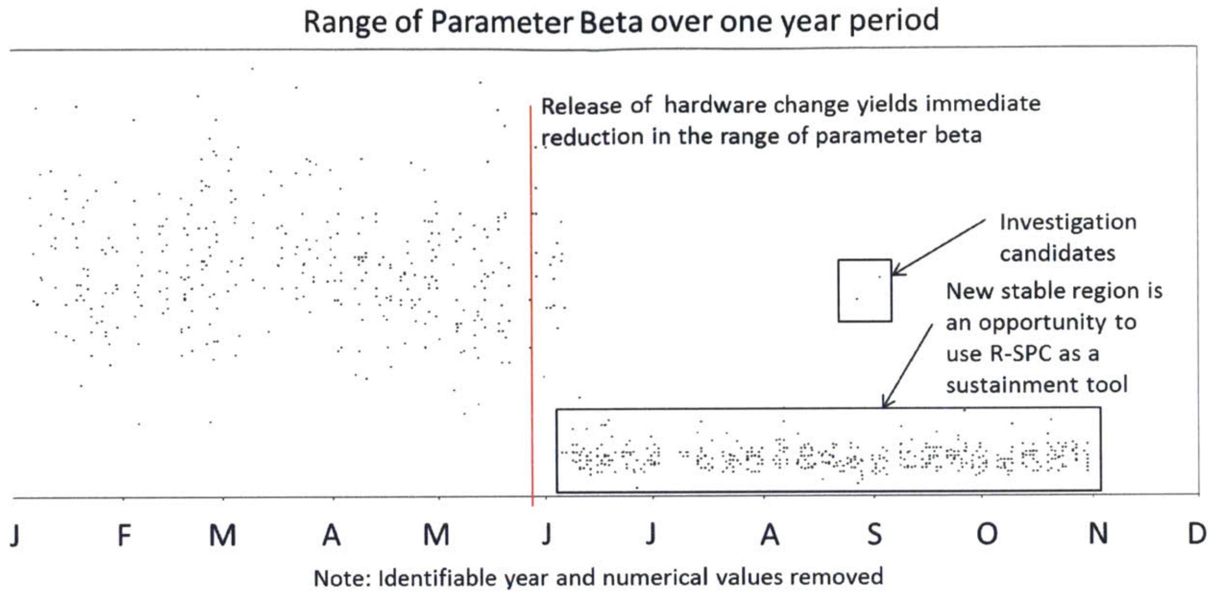

Figure 13: Parameter *beta* plotted over time. After a hardware design change was implemented, the range shrunk after the inventory of hardware was depleted during manufacturing

The date of the design change is marked by the red line in Figure 13. After depleting a small amount of old inventory, the variability of *beta* was significantly reduced.

In addition to observing the design change, it is possible to conduct the Chi Square test as in section 6.1. As in the example with the raw numerical characteristic *alpha*, instruments are grouped into one of three failure rate categories (0, 1, and 2+) and one of three level categories (high, low, and middle 33%). A summary of the counts for each are shown in Figure 14.

Level/Cat	0	1	2+	Total
H	122	44	115	281
L	175	32	43	250
M	189	43	63	295
Total	486	119	221	826

Figure 14: Numerical count for high, low, and medium values of *beta* by instruments with 0, 1, or 2+ failures within 90 days of shipment during an eight-month manufacturing period

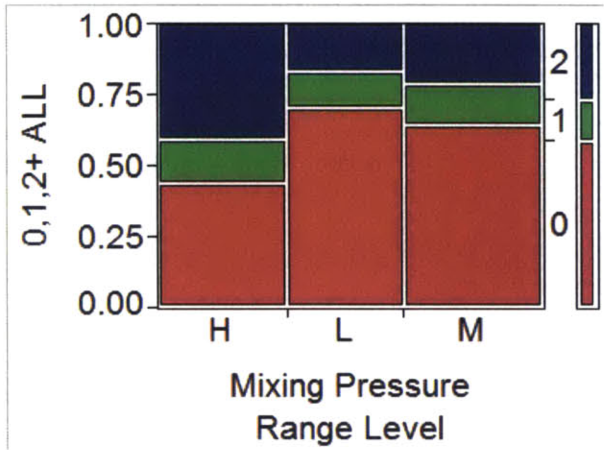

Figure 15: Visual breakdown between high, low, and medium values of *beta* by instruments with 0, 1, or 2+ failures within 90 days of shipment for instruments manufactured during an eight-month period

From the 3x3 table, it would be expected that instruments experiencing zero service calls would be equally likely to fall in the low, middle, and high categories. However, it is clear that this is not the case with 122 instruments falling into the High category, 175 falling into the low and 189 falling into the medium category. The test statistic turns out to be 51.62, which far exceeds the threshold of 9.49. The p-value is <.0001 as shown below.

N	DOF	Test Statistic	Threshold	P-value
826	4	51.62	9.49	<.0001

Figure 16: Summary of statistical results for *beta* showing a p-value of <.0001; there is enough evidence to reject the null hypothesis and conclude that the level of mixing pressure range may have contributed to this failure mode

Such a low p-value suggests that it is unlikely to find an outcome at least as hostile to H_0 as the outcome found here. As a result, we can reject the null hypothesis and conclude that the tallies in each of the categories were not due to random chance alone. It is reasonably likely that the level of *beta* is NOT independent of the number of ESCs that occur within 90 days. Compared to *alpha*, this example demonstrates that this parameter may be more amenable to monitoring in R-SPC.

6.3 Standard Work Improvements

A variety of changes were made to R-SPC standard work including a troubleshooting guide and an improved examination process for instruments. These changes streamlined the workflow and improved the efficiency with which instruments could be examined on the floor.

One area of noticeable improvement was in the number of SPC events that occurred per unit time due to the reduction of monitored numerical characteristics. Figure 17 below shows the number of SPC trigger emails received per instrument produced. At various points in the deployment of R-SPC, the number of events reaching the team was exceeding the team's ability to examine instruments on the floor.

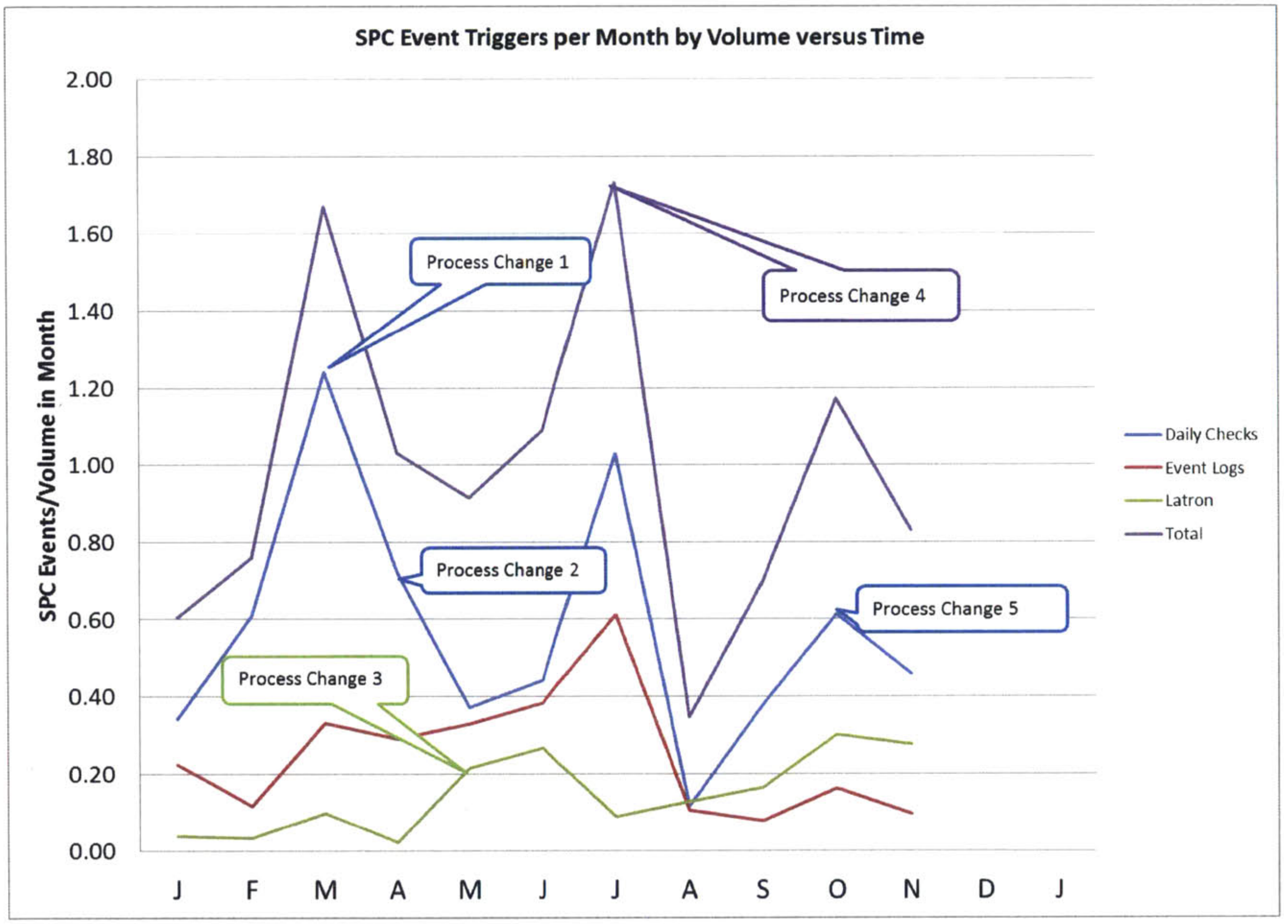

Figure 17: Number of SPC Events per instrument production volume in month

After reducing the number of monitored parameters in August to approximately 20, the number of events per instrument dropped significantly. Focusing on fewer numerical characteristics allowed the team to spend more dedicated effort on fewer Gemba examinations.

In addition to reducing the number of monitored numerical characteristics, several methods were improved through creation or change of standard work. Specific examples are mentioned below, with several others detailed in the appendix.

6.3.1 Daily Management Instructions

In order to conduct meetings efficiently, Daily Management must have a prescribed sequence of events. Figure 18 is an example of how listing the R-SPC objectives, schedule, and agenda can be achieved in a concise format. Such standard work is posted in the meeting area so that all participants understand their responsibilities and meetings stay on track.

SPC Daily Management Agenda

Objective:

- Reliability Improvement Initiative to review characteristics critical to quality and quickly escalate to resolve issues and reduce Emergency Service Call rates.

Location:

- Building 5 Viscaya / MRM

Meeting Frequency / Time:

- Monday / 9:00 – 10:00 AM
- Wednesday, Friday / 9:00 – 9:30 AM

Daily Agenda:

	Mon	Wed	Fri
Action Items	Y	Y	Y
New SPC Trigger (Event)	Y	Y	Y
Open Investigations	MIM	MRM/MIM	MIM
Other business and summarize	Y	Y	Y
Trending	Y		

Figure 18: Daily Management Standard Work Agenda Excerpt

6.3.2 Troubleshooting Guide

A "Troubleshooting Guide" was also established to recommend key items to look for when a team member visits the Gemba in response to an SPC trigger. Before conducting their own examination, the guide provides a list of known symptoms and their likely root causes for the team member to review. Only after options in the guide are exhausted will the team member continue the examination using other methods such as escalation to another team member. This approach saves time and helps less familiar team members learn the R-SPC process.

7 Case Studies of selected Trends in Instrument Manufacturing

The following describes two cases where R-SPC was utilized to identify trends during instrument manufacturing. Aspects of the case have been modified to preserve confidentiality.

7.1 Case Study 1: Numerical Characteristic *alpha*

The cross functional R-SPC team conducted several instrument examinations resulting from R-SPC triggers from outliers observed in *alpha*. The numerical characteristic exhibited a general upward trend over the course of several weeks as shown in Figure 19 and Figure 20. Due to concerns about potential impacts to the ESC rate, the team opened a formal investigation to help identify the root cause of the increase. R-SPC's monitoring of *alpha* provided a logical starting point to begin the investigation.

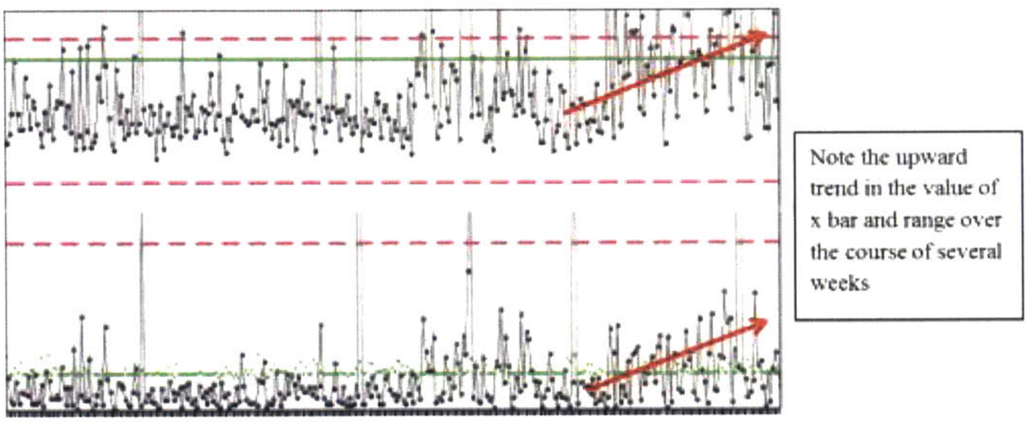

Figure 19: Numerical Characteristic *alpha* showing an upward trend in X-bar and subgroup range

Numerical characteristic *alpha* represents the number of particles counted during an empty sample run in a part of the DxH instrument. The measurement is a type of "background" count, and it is desirable to have such values be small so that any future sample measurement can have a particle count that far exceeds the background level. This ensures that the actual diagnostic test is not adversely affected by a large systematic error. A specification limit governs the acceptable upper value for this numerical characteristic during manufacturing (another wider limit governs the specification the customer must meet). In R-SPC, upper and lower control limits are set based on a historical period that showed particularly good process stability.

Every diagnostic test measurement is subject to error due to random fluctuations and systematic causes. To ensure that the systematic error is small, the DxH system performs a daily series of self-health checks during the "Daily Checks" sequence which typically occurs every day or after a long period of machine inactivity. During this sequence, empty samples are run through the system so that only bulk chemical reagents are part of the test. The type of chemical reagent passed through the system depends upon the type of test but usually includes diluent, a type of ionic solution, and/or a stain (a solution used to tag particles of interest). During this empty run, the number of particles is measured.

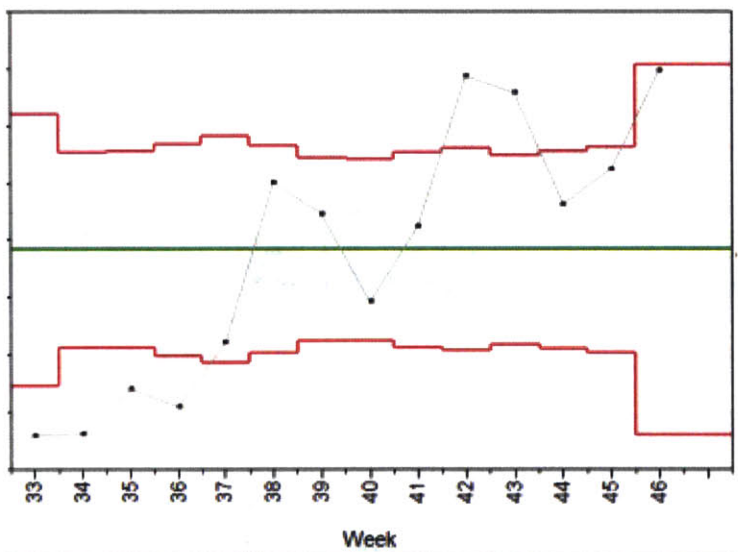

Figure 20: UWMA chart for numerical characteristic *alpha* showing an upward trend with data grouped by week

To investigate the root cause of the increase in *alpha*, several areas were examined including:

- The method for recording data from the daily checks sequence
- Recent hardware changes
- The chemical composition of the reagents
- Sequence of reagent use during manufacturing

To understand whether recording data from the daily checks sequence could be a trend, the raw data from recent trials were examined. The daily check sequence is run five times for each instrument during the manufacturing process quality control step to obtain the X-bar and range values plotted on the control charts. Very often, the first measurement of *alpha* is much higher than the others. After observing the behavior from the dataset, the team went to Gemba to conduct interviews with quality control technicians. The technicians indicated that this behavior is frequently observed and thus they always exclude the first daily check run since the system is not yet fully primed. When a system is not primed, air bubbles/debris in the sample lines may register as a particle.

The main cause of these bubbles and debris is that the machine has been physically moved from the integration and test stand to a new quality control test stand. Before the move, the system must be drained of all fluids in a shutdown sequence. Unfortunately, if the instrument is immediately reenrolled into ProService (see appendix 10.1.1), the R-SPC software records every daily check result provided from then on. Thus, if the first result is particularly extreme, the measurement is still averaged into the overall value of *alpha*. To mitigate the effect, the manufacturing process was modified to only enroll the DxH machine into ProService after the first daily check priming run is complete and the technician is about to begin the official quality control procedure. Changing the procedure will ensure that there is less variability in the measurement of *alpha*.

In addition to system priming, recent hardware changes were examined to determine if their implementation might contribute to the elevated background levels. One particular change regarding a manifold was scrutinized in more detail. The new manifold was implemented at a time similar when the increase in *alpha* was observed. The new design uses a barbed fitting to replace a machined manifold in order to reduce issues with particulate and trapped air. Upon further inspection, the hardware change was ruled out as a potential cause since the fluidic pathway does not directly interact with the pathway for *alpha* related material.

To understand whether chemical reagents used in recent production contribute to the elevated background count, it is necessary to examine retained boxes of the *alpha* related consumables available from storage. Each run consists of a mix of three consumables. Focus was directed towards the *alpha* clear and the *alpha* stain consumables. By revisiting these bulk reagent lots from storage and testing them using the same procedure conducted during their release, a direct comparison can be made to their record on file to see if there may be a trend.

Upon performing these activities for *alpha* clear, no significant change was noticed between the record on file at release and the recent test results. However, for *alpha* stain, a difference in the background count was observed between the record at release and the current observation. Upon interviewing a stain expert within the organization, it was determined that two things may be occurring (a) the test procedure calls for using a Z2 Coulter Counter, which is not directly comparable to the DxH system upon which the increase in particle counts was observed and (b) one of the main ingredients in the *alpha* stain is known to change slightly over its lifetime. When testing other known good *alpha* stains, similar results on the Z2 counter are observed. Finally, when testing *alpha* clear, *alpha* stain, and *alpha* diluent together in the DxH instrument, much lower particle counts were observed. As a result, though precipitation of *alpha* stain may be occurring, the degradation of the stain itself was ruled out as a root cause of the upward trend in *alpha*.

Though the stain itself was deemed not to be a concern, the sequence that the stain was used in manufacturing may play a role. When plotting the value of *alpha* over time and overlaying the use of consumable lot numbers in manufacturing on the same chart as shown in Figure 21, "out of sequence" lots are observed.

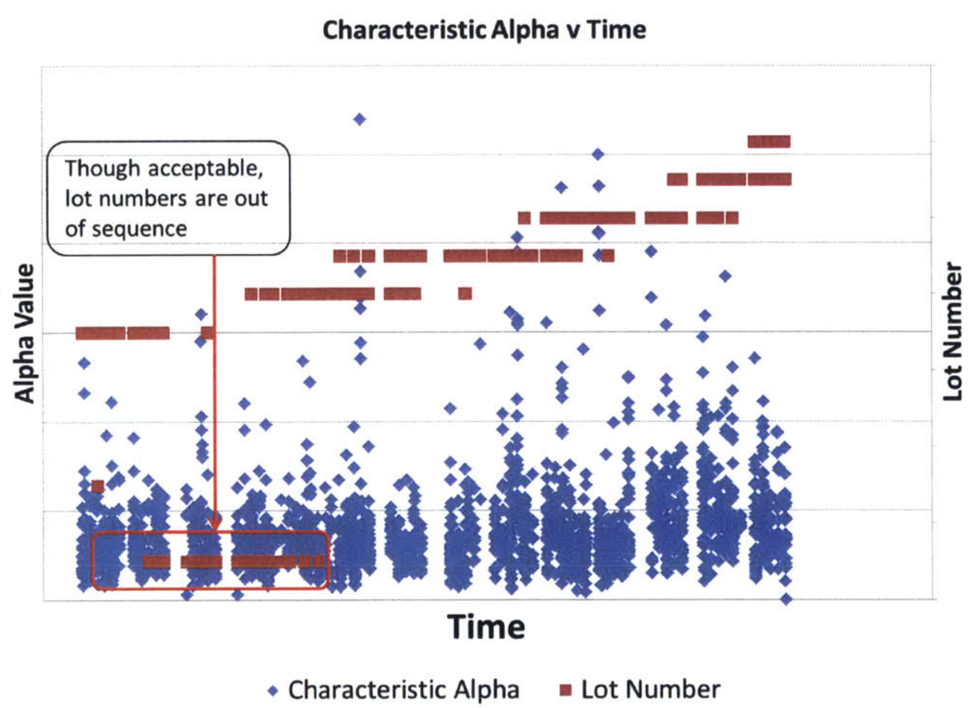

Figure 21: ***Alpha*** **consumables over time by lot number of showing out of sequence use in manufacturing (dates and values removed – period represents approximately a four-month period)**

Since reagent lots are manufactured in numerical order over time, older stains have lower lot numbers than younger stains. The result is that, in the short run, older stains may cause higher particulate counts to be observed by R-SPC due to out of sequence use. To counteract this effect, the manufacturing group was trained on how to pull the material in order by lot number to practice "first in, first out."

Overall, the investigation of *alpha* examined a variety of possible causes for the elevated level of the numerical characteristic. The R-SPC initiative was essential in opening this investigation and providing the appropriate data. Though each of the root causes identified were small, together they could impact the ability to identify reliability trends with R-SPC. Resolving each with an appropriate countermeasure, where necessary, helped to produce a better product for the customer and improve the problem solving capability of the R-SPC team.

7.2 Case Study 2: Debris Interference

Certain cell populations occur in relatively small quantities in the blood and can be counted using the flow cell portion of the DxH800 and DxH600 instrument. When the optical and electronic measurements recorded from the optical flow cell are aggregated together, software classifies cell populations by their numerical characteristics and displays the result visually. For example, a normal sample of blood would yield a cell pattern similar to Figure 22.

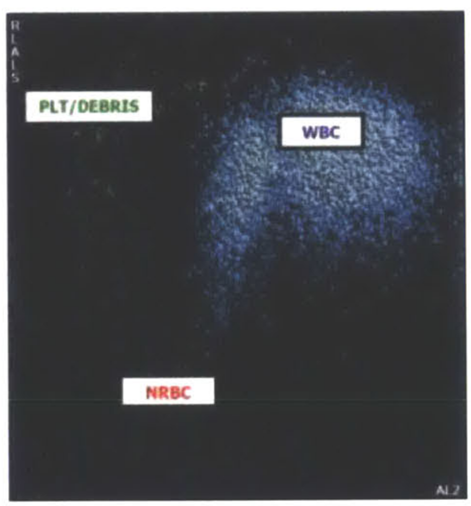

Figure 22: Normal Histogram showing populations of White Blood Cells (WBCs), Platelets and Debris (PLT/Debris) and Nucleated Red Blood cells (NRBCs)[15]

The white blood cell (WBC) population is largest, followed by the platelet grouping and then the Nucleated Red Blood Cells (NRBCs). When the system is working properly, the counts for healthy patient blood should follow a similar pattern. However, in some instances, extremely unusual patterns of WBCs, Platelets, and NRBCs occur. In these cases, patient results cannot be reported until the source of the unusual pattern is identified. The phenomenon, termed "Debris Interference," prevents certain cell populations from being accurately recorded. An example of such debris interference is shown in Figure 23.

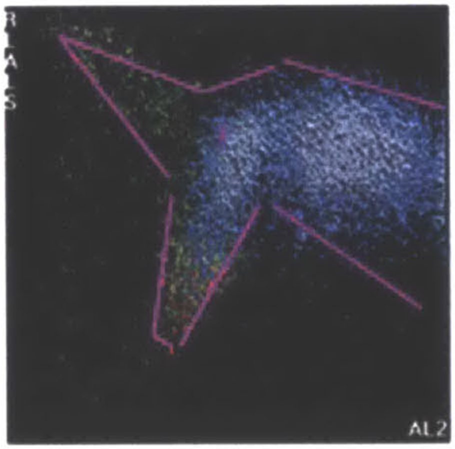

Figure 23: Abnormal Histogram showing populations of cells populations being obscured by a large number of debris events (provided by Research and Development group)

Note that the green events, classified by the instrument as platelets, obscure the small number of red NRBCs and makes it very difficult for the predictive algorithm to determine which cell population it is counting. Though the effect is extreme enough that a technician would readily throw out the results, the condition prevents further tests from being run and can result in instrument downtime or an ESC.

Eventually, the debris interference problem started to occur enough times to launch an investigation into the root cause. Ultimately the investigation revealed several contributing factors including:

- When a commonly used sample mode is disabled, one of the plastic sample lines can develop an air pocket over time that contributes to debris events occurring during data acquisition
- Improper mixing of the blood sample and reagents in one of the mixing chambers can cause debris particles to develop
- Improper mixing can be caused by (i) an instrument frame that is at the edge of its specification and/or (b) poor calibration of the Sample Aspiration Module (SAM) mounted to the frame.

Though these root causes likely contribute to the problem, they are difficult to detect on their own during the manufacturing process. For instance, to identify an out of specification frame would require a costly and time intensive inspection step. Though this might be possible to accomplish more easily with a test fixture, such a fixture would need to be designed. To get around these issues in the short term, the team identified a numerical characteristic that correlated with the presence of debris interference. The numerical characteristic was discovered by looking at many historical examples of the debris interference failure mode and constructing a fishbone diagram. During a sample run, the sample is run through the flow cell until 8192 events are counted or the system times out. It was noted that if the number of events, called "analyzed" was too low, that there was a high chance that the system would exhibit the failure mode. As a result, it was possible to set a threshold under which further action could be taken in manufacturing to inspect the instrument. In particular, if the number of analyzed events divided by the expected 8192 events was less than the criteria, action would be taken to inspect the instrument and take preventive measures such as SAM realignment.

By identifying a simple ratio of interest, R-SPC was able to frequently detect debris interference cases in manufacturing prior to shipment. Though identifying the symptom could not solve the root cause of the overall problem, it allowed for appropriate intervention of short term countermeasures to prevent potential reliability issues from arising at the customer site while design changes were made.

8 Conclusions

8.1 Summary of findings

This project sought to test several hypotheses about the extent to which the R-SPC initiative improves reliability of the DxH800 and DxH600 manufacturing line. Through a statistical analysis using the Chi Squared Test, it was determined that some numerical characteristics monitored by the team do not appear to have a strong relationship to the number of emergency service calls instruments experience within 90 days of manufacturing. By contrast, other parameters derived from combinations of numerical characteristics might be beneficial to the R-SPC cross functional team. The goal of monitoring any variable is to identify trends, positive or negative, wherever they occur in manufacturing so that reliability can be improved through appropriate countermeasures. For instance, the analysis of parameter beta in section **Error! Reference source not found.** suggests that other statistics not now emphasized might be more promising in this regard.

8.2 Key Recommendations

Statistical Process Control is a valuable core capability in the organization and should be applied wherever possible. The R-SPC initiative is one such example of this idea. Though Beckman Coulter already runs a robust quality control program, applying R-SPC to help identify trends in manufacturing will assist in improving reliability of the DxH product line. Eventually, the methods established can be transferred to other product lines to address similar reliability improvement goals. Based upon the analysis conducted in this thesis, the following actions should be undertaken

Immediately:

- Conduct regular training for Statistical Process Control methods
- Launch updated tools with control limits, notifications, and visualization
- Improve the funnel of improvement projects
- Focus on trends, positive and negative, to understand their origins
- Sustain Daily Management schedule and regular observations at Gemba via electronic notifications

Next Steps

- Allocate development resources to implement new feature list for ProService tool
- Conduct additional statistical tests to evaluate against 90 day instrument ESC rate
- Support Kaizen event to integrate instrument and reagent manufacturing R-SPC efforts

Long term

- Merge tools into one user facing Web-based platform
- Transfer to other product lines to continue reliability improvements
- Use different KPIs to measure R-SPC effectiveness; ESC reduction does not measure uptime or averted problems
- Reevaluate specification limits to ensure alignment with the "voice of the process"

8.3 Future work

This project focused heavily on the manufacturing of the instrument portion of the DxH product line. Many opportunities also exist for the manufacturing portion of the reagents used on the DxH. A future project might include further study of variation in reagent manufacturing, including how the instrument manufacturing environment can serve as an early warning system for the customer.

An additional avenue of study could leverage the large dataset available from instruments deployed in the field. Such data could be used to build statistical evidence in support of additional numerical characteristic monitoring in other contexts.

9 References

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10 Appendix

10.1 Data sources

The following describes several data sources used and the methods employed to sort the information. **Note:** Some screenshots have been removed for confidentiality purposes.

10.1.1 ProService

ProService is an application that collects data from any compatible, connected instrument. A variety of products are supported by ProServive, however, the discussion here is limited to the data collected on the DxH800 and DxH600 products. ProService can be deployed on customer sites for those customers that have stable internet connections and who opt in. One use case of the application is to support customer service interactions. For example, when a customer calls in with a problem, a trained technician can remotely access the instrument and help evaluate and resolve the problem. In such cases it may be possible to avoid sending a service technician.

Another use case is to collect data from an instrument in the field over time to determine if that instrument is likely to experience a problem in the near future. This type of interaction is more proactive since technicians are able to step in to address a problem before it might occur. The field service group is currently looking for ways to use this data more effectively to anticipate field failures; however, implementation thus far has been limited.

Examples of several numerical characteristics originally believed to be related to reliability are shown below. The "Potential Problem Code" column, an internal mapping to a descriptive category technicians fill out while servicing an instrument on site, is an initial hypothesis for what problem codes may be related to an unusual value of the characteristic.

Numerical characteristic	Potential Problem Code	Data Table
BKG_RETIC_NUMEVENTS	102, 103, 802, 110, 304	Daily checks
BKG_WBC_UNCRRCTD_VALUE	102, 304, 306, 112, 802	Daily checks
BKG_PLT_VALUE	102, 304, 306, 112, 802	Daily checks
VCSLATRON_NRBC_ALL_CV	102, 301, 501, 504, 504, 1401, 107	Latron
VCSLATRON_NRBC_MALS_CV	102, 301, 501, 504, 504, 1401, 107	Latron
VCSLATRON_NRBC_UMALS_CV	102, 301, 501, 504, 504, 1401, 107	Latron
VCSLATRON_DIFF_RFPEAK_MEAN	102, 107, 112, 301, 304, 1401	Latron
VCSLATRON_NRBC_ALL_MODE	N/A	Latron

Figure 24: Eight selected numerical characteristics monitored with the R-SPC initiative

In the case of R-SPC, ProService is deployed as a method to collect data about the instrument during manufacturing. It is an additional data source that is not formally part of the quality control system or design service record submitted for regulatory compliance. As a result, the data can be used for strategic and business purposes, such as to identify methods to improve product reliability. The data drawn in R-SPC from ProService comes from three main tables: "Daily Checks," "Latron," and "Event Logs." The contents of each are summarized below:

10.1.1.1 Daily Checks

Contains continuous numerical characteristics from the DxH system running a daily startup routine to verify that the instrument is prepared to run samples. During final test, the quality control group runs a "Daily Check" five consecutive times to verify that the results are within specification. If the results are all within specification limits, the instrument is allowed to ship. R-SPC takes these five data points and plots their average and range on a control chart.

10.1.1.2 Latron

Contains continuous numerical characteristics related to Latron, a substance consisting of synthetic particles used to calibrate the instrument. Similar to Daily checks, a series of Latron bead particles are run through the instrument directly before the quality control steps.

10.1.1.3 Event Monitoring

Contains attribute information about the instrument state (i.e. event occurred). During the set of Daily Checks run during final test, various "soft errors" can occur in software. These include warnings such as "Probe_Home_Recovered" among others. These messages do necessarily point to a critical system fault, but their frequency may indicate something about an instrument's state during manufacturing. Such soft events do not prevent an instrument from shipping since they typically do not affect the machine integrity.

10.1.2 Oracle Business Intelligence (OBI) and Oracle Business Objects (OBO)

Oracle Business Intelligence and Oracle Business Objects store a significant amount of business data including sales, supplier information, and service records. OBI is the newer platform and a significant amount of data found in OBO can be found in OBI. Eventually all data from OBO will be migrated to OBI since the platform is easier to use and manage for the end user.

An extremely important record used in this project was the field service history for DxH instruments. Though OBI has detailed records, OBO still has more complete, detailed information, including problem codes and resolution codes that the service technician uses to classify the problem they encountered. Though there are some open questions as to the accuracy of the problem codes, they do provide a way to objectively place service calls into buckets. This is useful for conducting statistical tests such as Chi Squared.

10.1.3 Linking ESC data to instruments in manufacturing

In order to compare an instruments manufacturing state to its field performance, the field records from OBO were compiled and cross referenced with the appropriate serial numbers. One of the difficulties in compiling this data was that the nomenclature for identifying unique instruments differed between databases. The ProService database uses a primary key called, "external instance number" which consists of the product type, year produced, and a unique number. This number is distinct from the serial number found in the Oracle system.

To link these data fields together, a large excel spreadsheet was constructed to combine instance numbers in ProService with serial numbers from the service record. For every measurement in ProService, the number of service calls the instrument received within 90 days of field usage was recorded. This was accomplished using pivot tables and the "index" and "match" functions in excel. The result was a table similar to the following simulated format:

serial_no	Min(Date)	90 Day Failure Count ALL	0,1,2+ ALL	90 day ESC (Codes 301-307 and 204)	0,1,2+ Code 301-307 and 204	Characteristic Value	Characteristic Value Level (L, M, H)
12345678	Jan 1	1	1	0	0	4	L
…	…	…	…	…	…	…	…

Figure 25: Arrangement of data in preparation to conduct Chi Squared Test

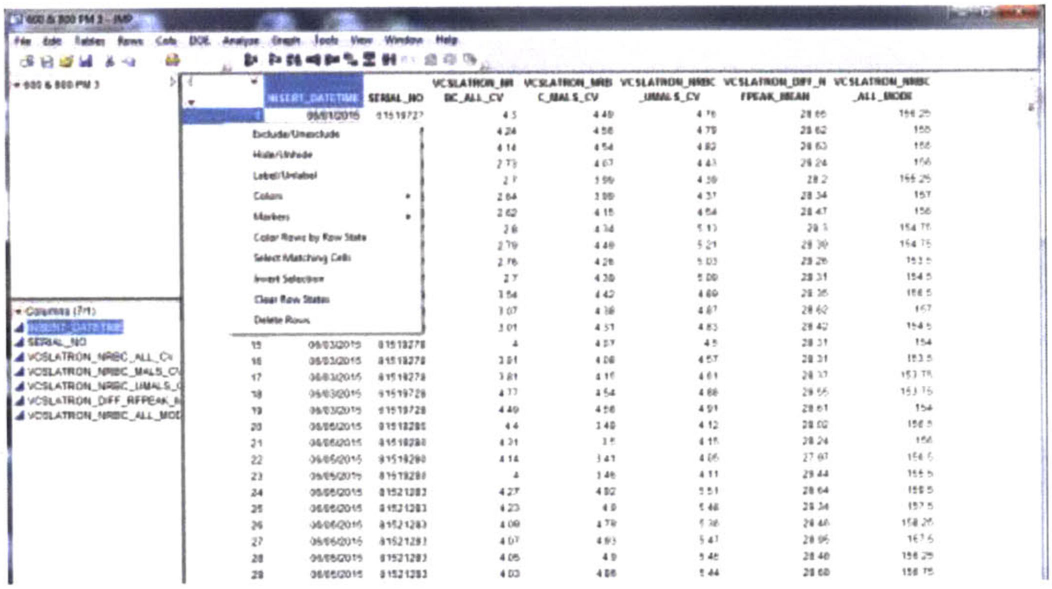
Subsequent to arranging the data in this format, the columns could be transferred into JMP for further statistical analysis.

10.2 Methodology for Calculating Control Limits for R-SPC using JMP

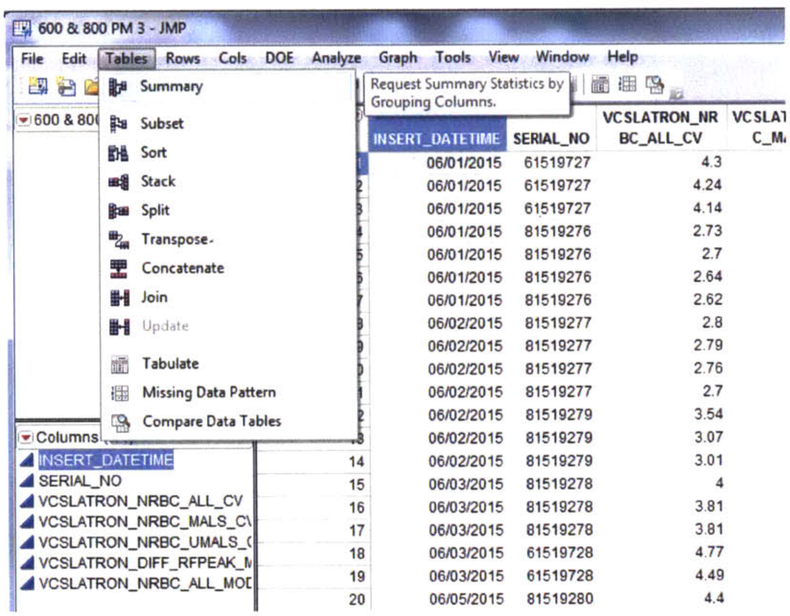
The following instructions summarize a manual process for calculating control limits for reliability SPC X-bar and Range charts. These charts plot the average value (X-bar) and the range of a subgroup of measurements for a particular numerical characteristic of interest. The goal is to generate limits that are reasonable given the "voice of the process." It is assumed that the effects of varied subgroup sizes are minimal and that the process data is drawn from a "reasonably" stable period." Typically, at least 60 unique subgroup measurements should be taken. The control limits are NOT dependent whatsoever on any specification limits (the so called, "voice of the customer"). Though it is hoped that the "voice of the process" aligns with the "voice of the customer," this is not always the case.

Control Limits should be recalculated whenever a process change is made that may affect the numerical characteristic of interest.

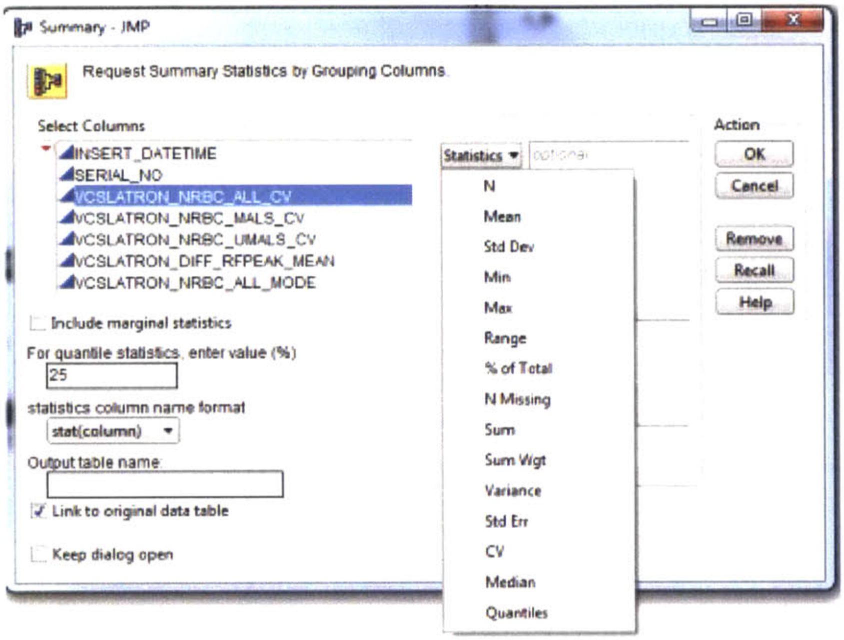
1.) Extract raw R-SPC data for a "stable" period into a separate excel file.
2.) Copy "insert_datetime," "serial_no" columns and the desired numerical characteristics columns into a new excel sheet.
3.) Sort the data by serial number and then by date using Excel's sort function.
4.) Use the "subtotal" function "min" on "insert_datetime" to identify the beginning of a subgroup and sort by the min "insert_datetime." Remove the subtotals. The data should now be sorted by serial number with the first appearance of a serial number controlling the order of the data.
5.) Copy the columns into a JMP data table
6.) Right click on a row and select "clear all row states"



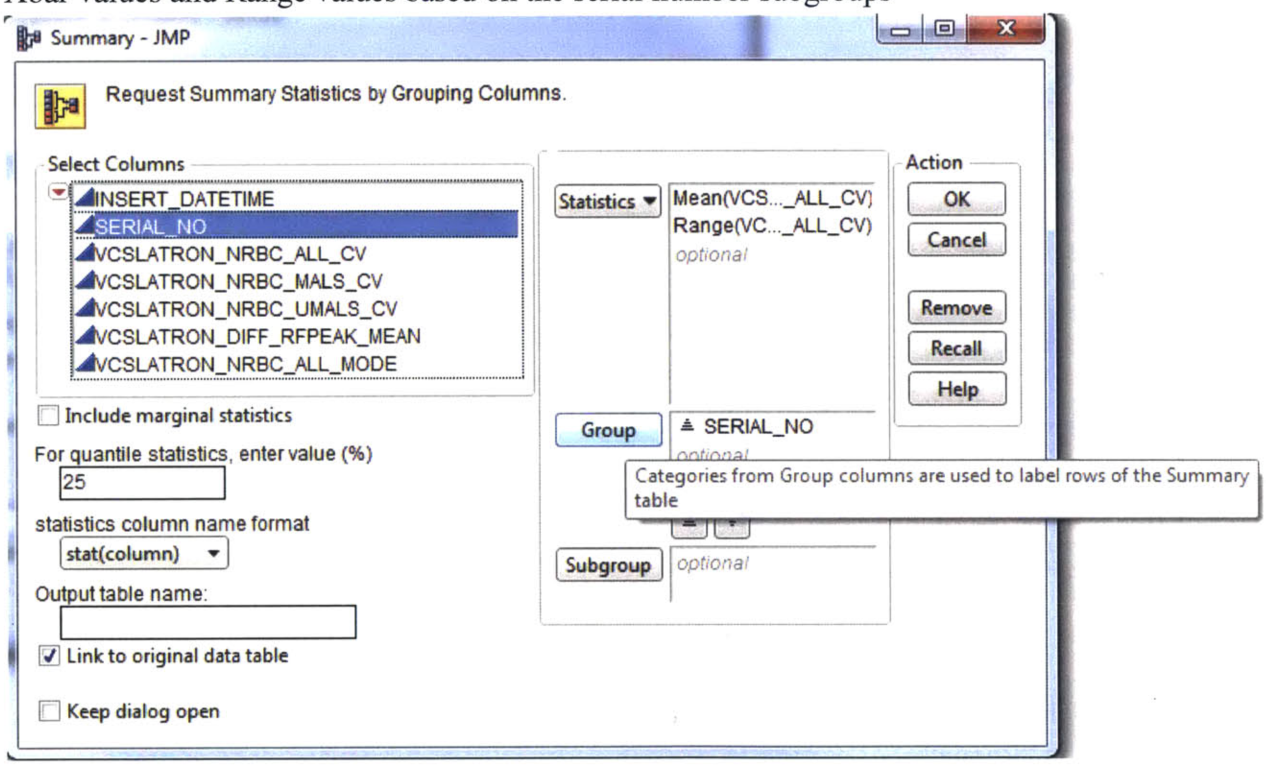
7.) Click, Table -> Summary to open the dialog box to compute means and ranges for the data



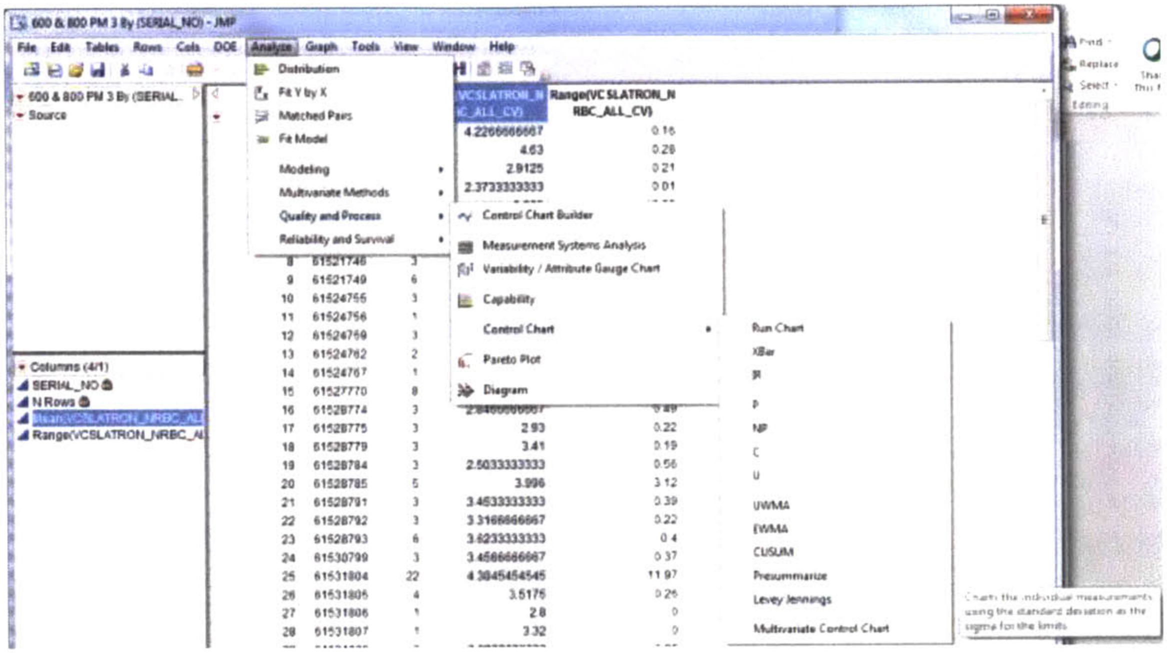
8.) Select the numerical characteristic of interest and then click "Statistics" to add, "Mean" and "Range"



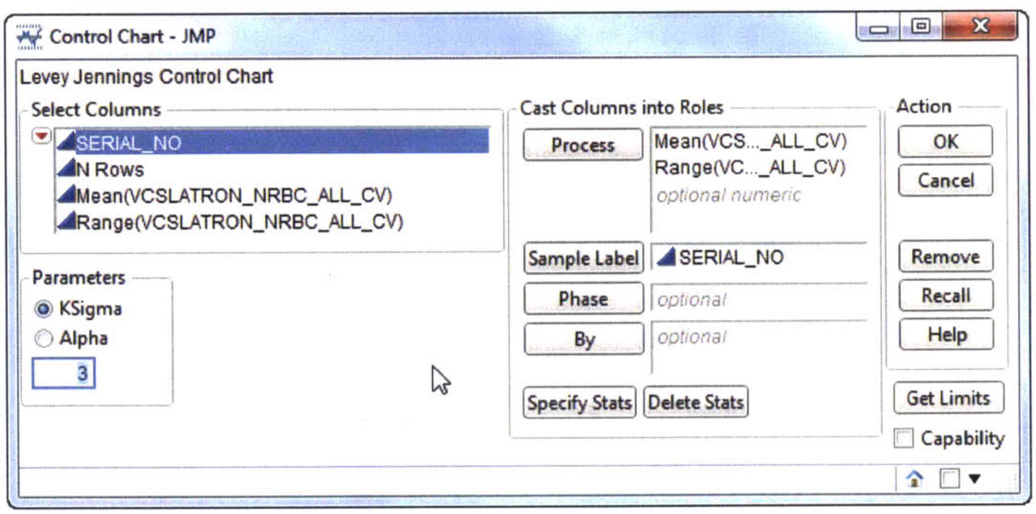
9.) Select “SERIAL_NO” column and click “Group.” Click “ok.” This will create a table of Xbar values and Range values based on the serial number subgroups



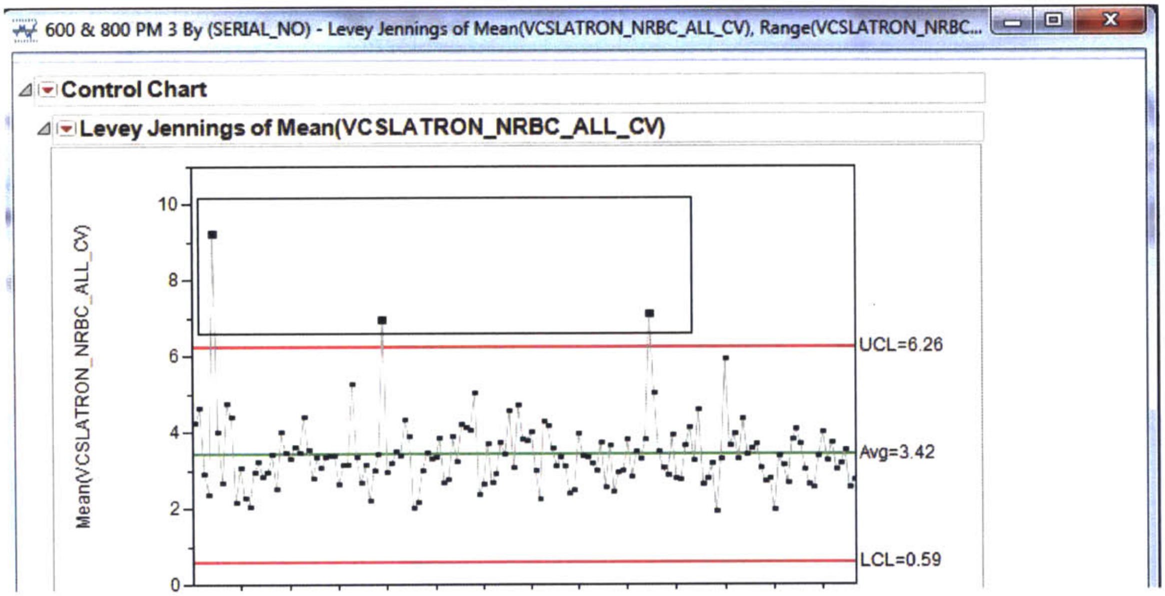
10.) In the new table, click Analyze -> Quality and Process -> Control Chart -> Levey Jennings. This approach is used since the data has been “flattened” to be individual Xbar and range points.



11.) Add the Mean and Range to the "Process" and add "SERIAL_NO" to the Sample Label. Click OK

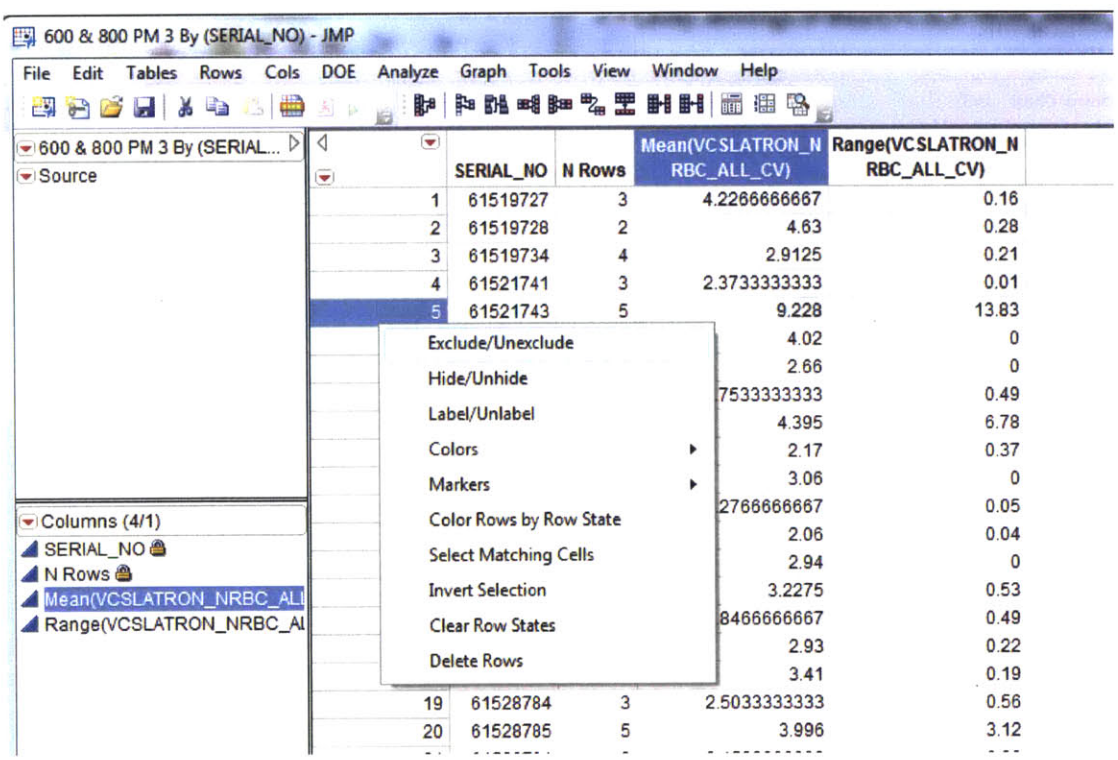


12.) Drag and select the points that reside outside of the control limits



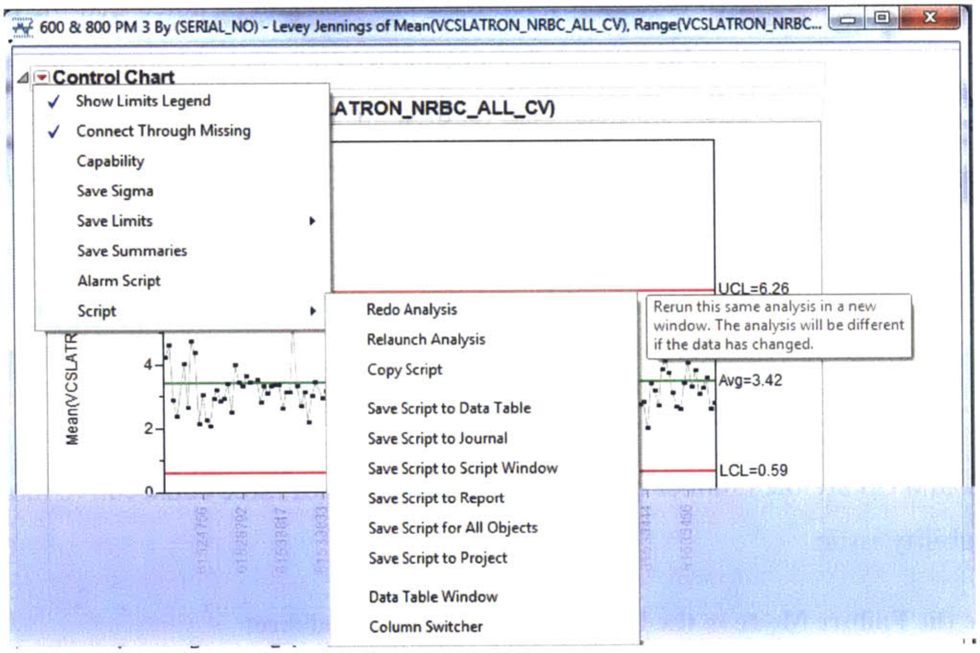
Repeat for the range

13.) Go back to the data table and press "F7" to find the nearest selected points. Right click and select "Exclude/Include" AND "Hide/Unhide"

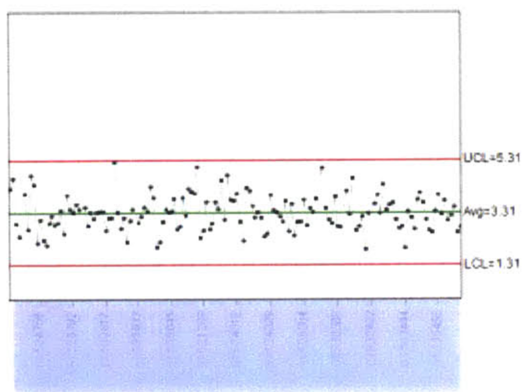


The following two symbols will be shown on the row when both of these commands have been completed:

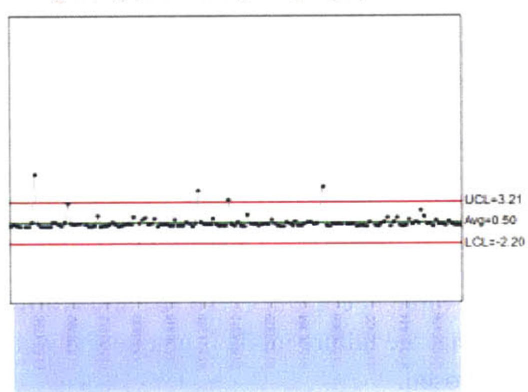
14.) Return to the graph window and select the drop down triangle and select "script" -> "redo analysis"



15.) The newly calculated control limits should be used for the numerical characteristic X-bar and R chart



Jennings of Range(VCSLATRON_NRBC_ALL_CV)



10.3 Methodology for Calculating ESC Rate

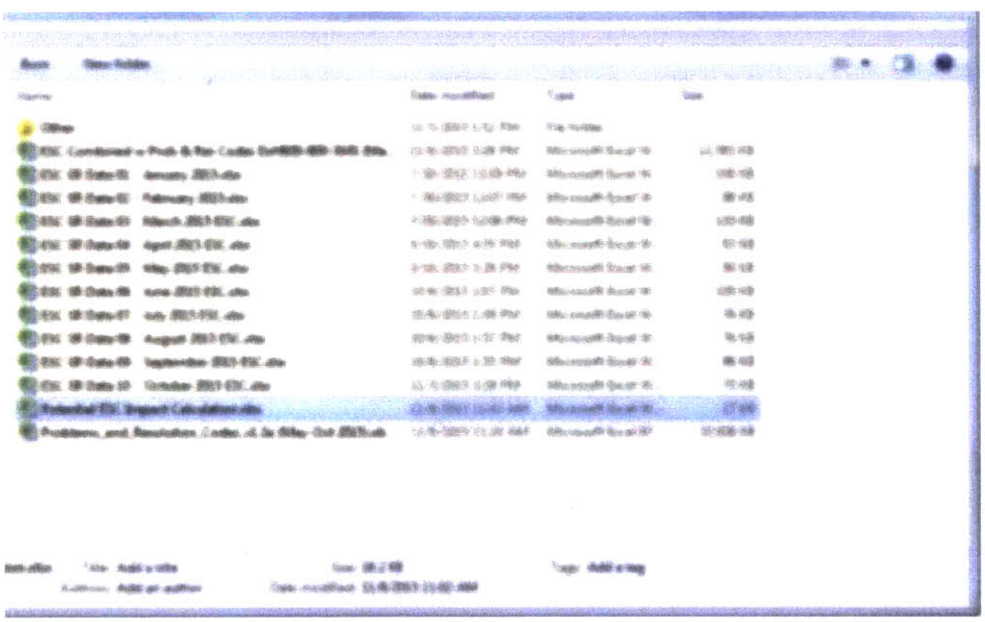
The following instructions describe a method to calculate the estimated ESC value of an identified failure mode in terms of emergency service calls. It should be noted that the method is highly inexact since qualitative engineering judgment and reliance on field comments is used. Despite the potential for noisy measurements, the method provides some understanding of the prevalence of a failure mode and is therefore beneficial in developing a strategy for next steps. This method focuses primarily on reliability issues for the DxH800 and DxH600. The ESC rate for a particular reliability issue is defined as:

$$\frac{Average(C1, C2, C3) * 12}{Install\ Base} * (Predicted\ Contribution)$$

where C1, C2, and C3 are the number of ESCs detected in each of three consecutive months for a particular reliability issue.

Part A: Define the Failure Mode in the Impact Calculation Spreadsheet

1.) Navigate to the folder: ~\ESC Calculation
2.) Open the file "Potential ESC Impact Calculation.xlsx"



3.) Enter the name of the identified failure mode in column A and choose a unique fill color for the cell.
4.) Identify keywords that correspond to the failure mode and enter them into column B.
5.) Choose a "Predicted Contribution" value in column C. To be conservative, the default value is 0.4. If there is a high degree of certainty that the failure mode is unique and well identified in the field record, a value of 0.6-0.8 can be chosen.

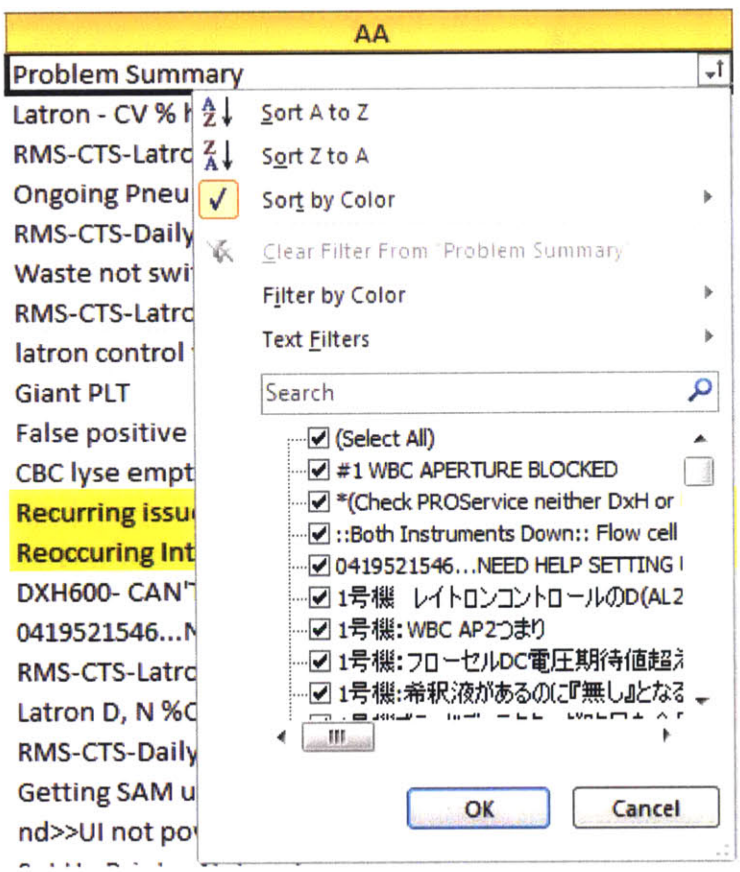
6.) If there is a related SPC trigger, enter it in column D.
7.) Save the file and keep it open to enter more data in later parts of this document.

Part B: Count the number of Failures in Warranty Data

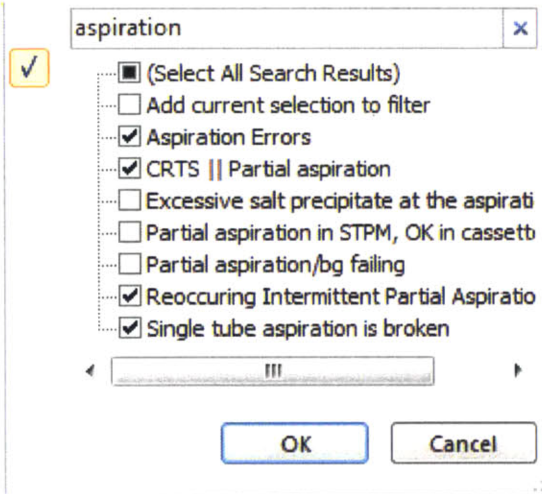
8.) Navigate to the folder: ~\PD L1 SPC\ESC Calculation and identify the list of files with the naming convention, "ESC SR Data [MM] – [Month] [YYYY] ESC.xlsx"
9.) Open the file of the most recently completed month.

The data contained within is a list of service records that occurred within the month for those instruments still within the 1 year warranty period. Ensure that the "filter" mode is turned on in excel so that the columns can be searched and tagged.

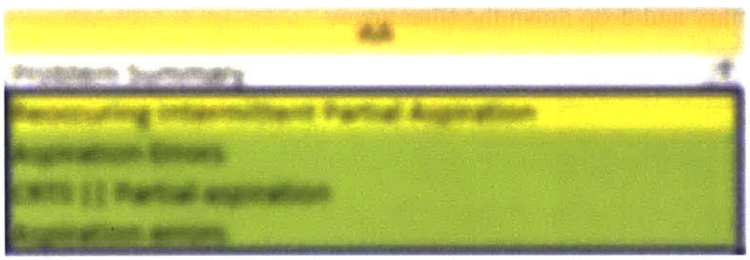
10.)Scroll over to column AA "Problem Summary and drop down the filter arrow



Enter the first keyword in the "search" field and examine the results. Leave checked ONLY the problem summaries that correspond to the intended failure mode.

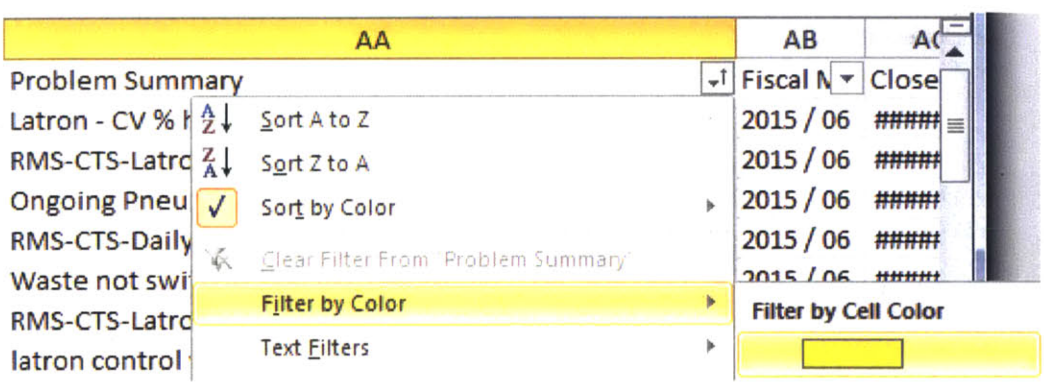


11.)Click "ok" and fill the remaining cells with the unique color selected in part A.

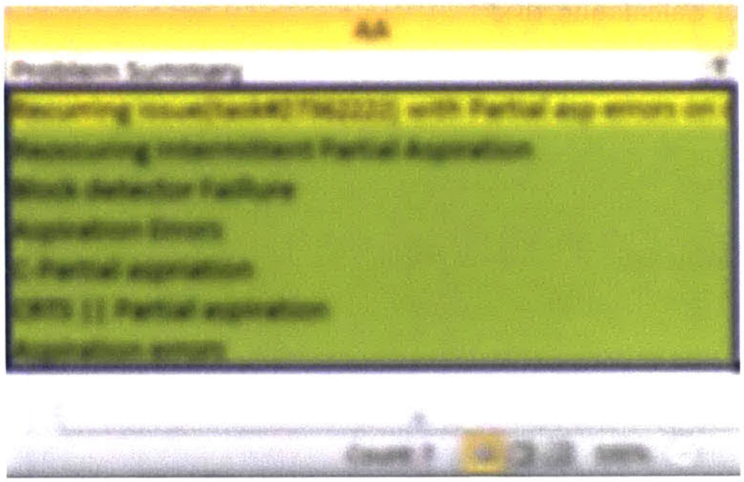


12.)Repeat steps 10 and 11 for all remaining keywords, tagging all relevant service records with the unique color.

13.)When the search is complete, click the filter arrow and choose "Filter by Color," selecting the unique color used to tag the service records



14.) Count the total number of service records



15.) Save and close the service record file and navigate back to the "Potential ESC Impact Calculation.xlsx" file.
16.) Scroll to the right to enter the service record count into the appropriate month.
17.) Repeat Part B to obtain service record counts for at least 4 total months total

Part C: Computing the ESC Rate

18.) Verify that the most recently completed month has the install base value.
19.) Compute the Emergency Service Call rate in month using a three month rolling average.

$$\frac{Average(C1, C2, C3) * 12}{Install\ Base} * (Predicted\ Contribution)$$

With four months of data, two, three-month rolling averages can be computed (for the current month n and n-1).

20.) Copy the most recently computed value into column G, "Predicted ESC Value." This value should be used as an approximation of the ESC impact that can be achieved through implementing a relevant countermeasure.

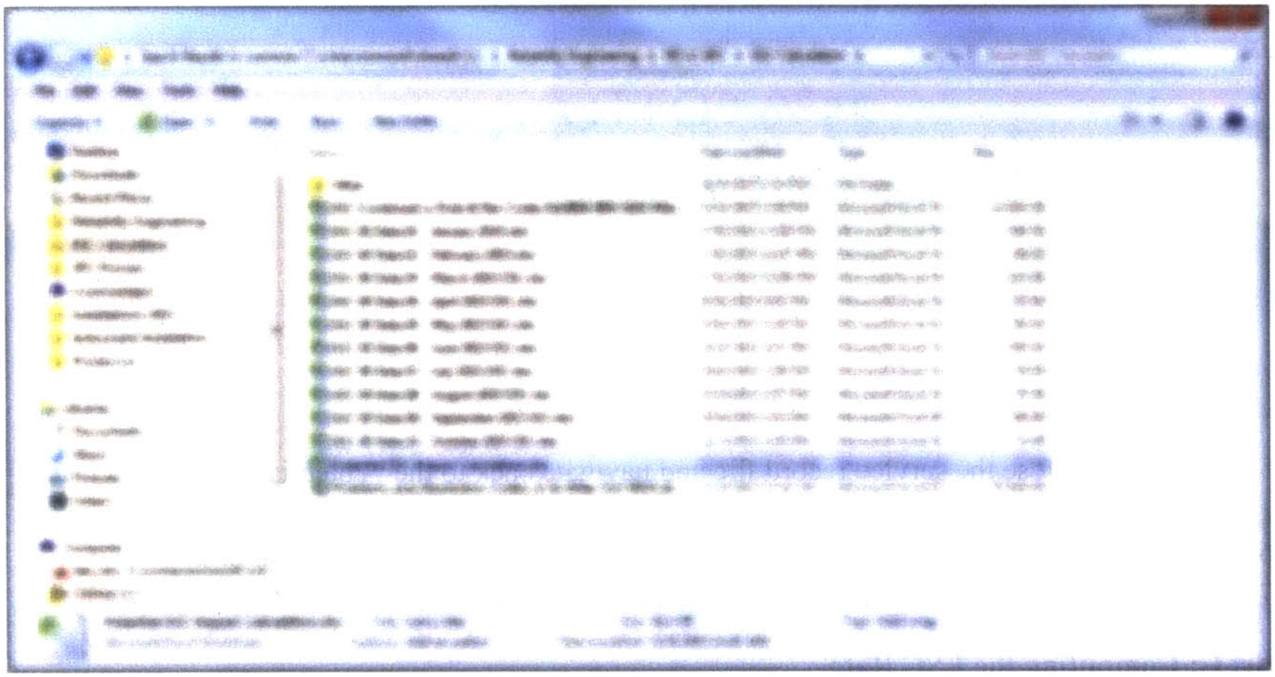
D. Calculating Sustainment

The following instructions describe how to calculate the ESC rate for a failure mode after a corrective action is implemented. It is assumed that the corrective action only affects new instruments manufactured after the cut in date of the change.

Repeat the following procedure for each failure mode

21.) Navigate to the folder: ~\PD L1 SPC\ESC Calculation

22.) Open the file “Potential ESC Impact Calculation.xlsx”

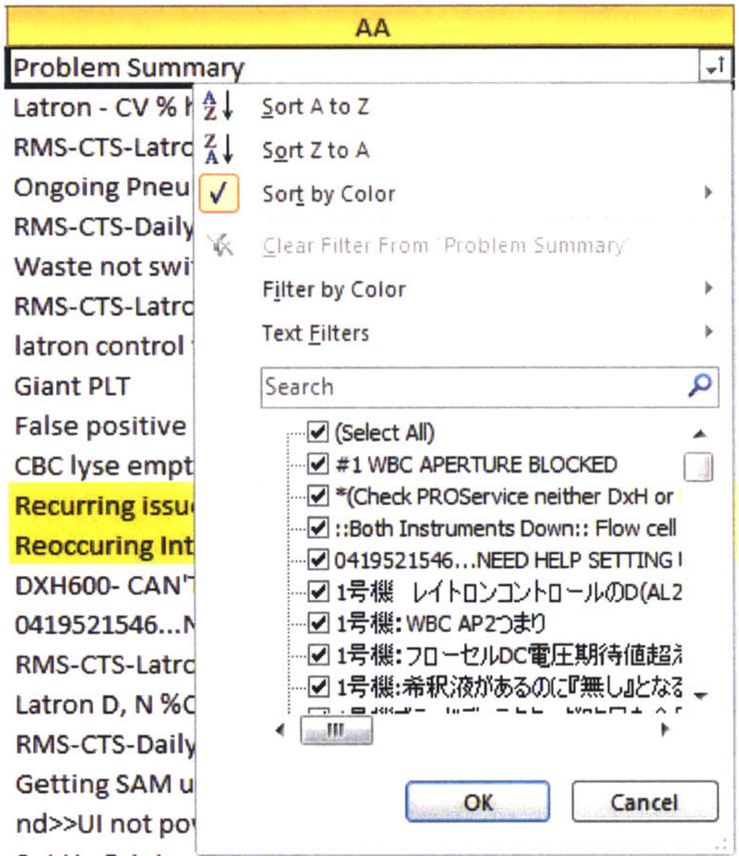


23.) Identify the cut in date of the corrective action.

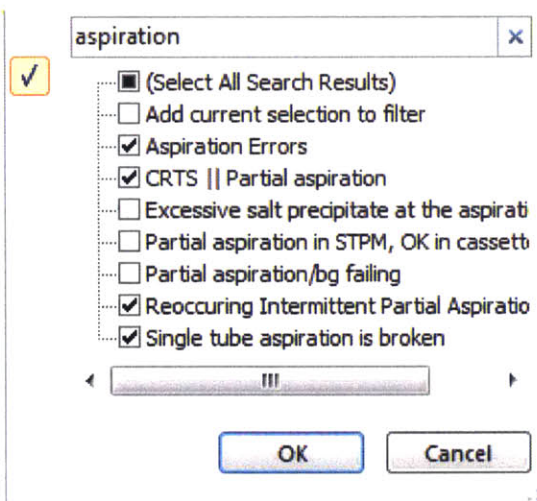
Open the file with the same month with the naming convention, “ESC SR Data [MM] – [Month] [YYYY] ESC.xlsx”

The data contained within is a list of service records that occurred within the month for those instruments still within the one-year warranty period. Ensure that the “filter” mode is turned on in excel so that the columns can be searched and tagged.

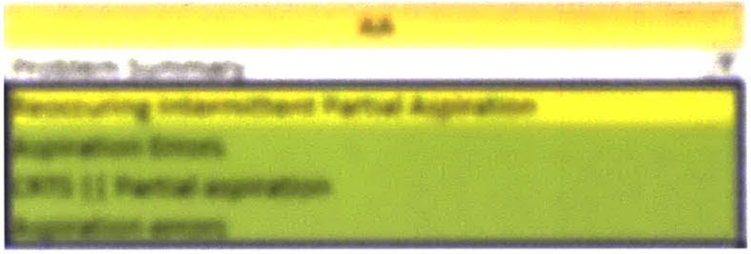
24.) Scroll over to column AA “Problem Summary and drop down the filter arrow



Enter the first keyword in the "search" field and examine the results. Leave checked ONLY the problem summaries that correspond to the intended failure mode based on the keywords AND have occurred AFTER the cut in date of the failure mode in question.

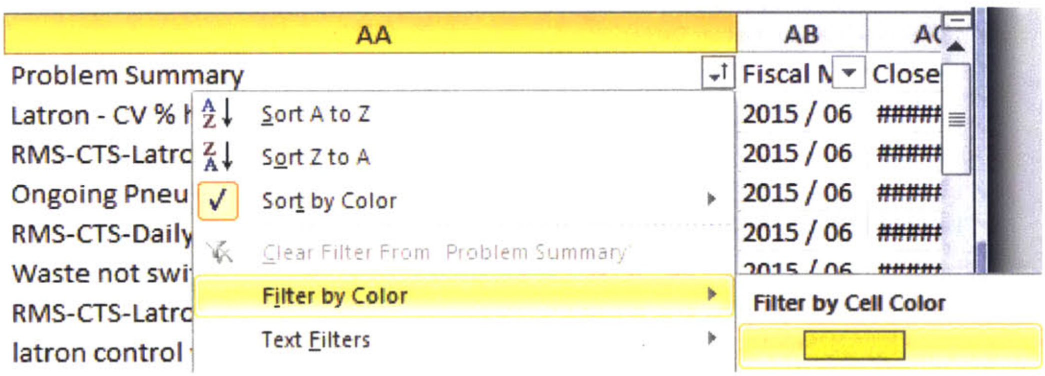


25.) Click "ok" and fill the remaining cells with the unique color selected in part A.

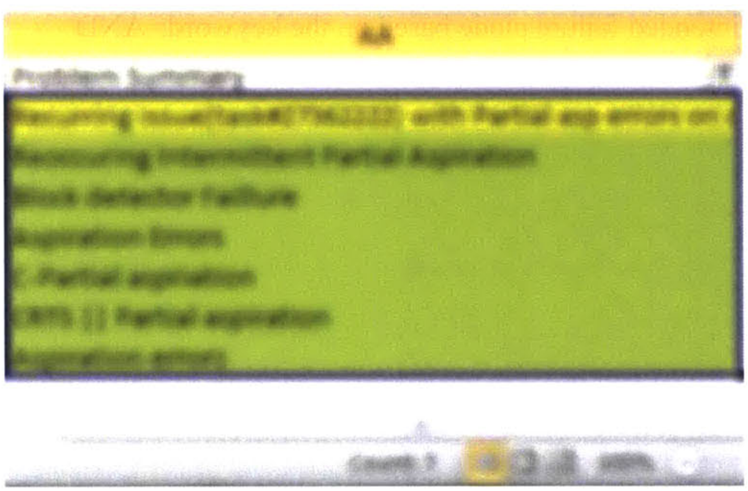


26.) Repeat steps 10 and 11 for all remaining keywords, tagging all relevant service records with the previously chosen color for the failure mode.

27.) When the search is complete, click the filter arrow and choose "Filter by Color," selecting the unique color used to tag the service records



28.) Count the total number of service records

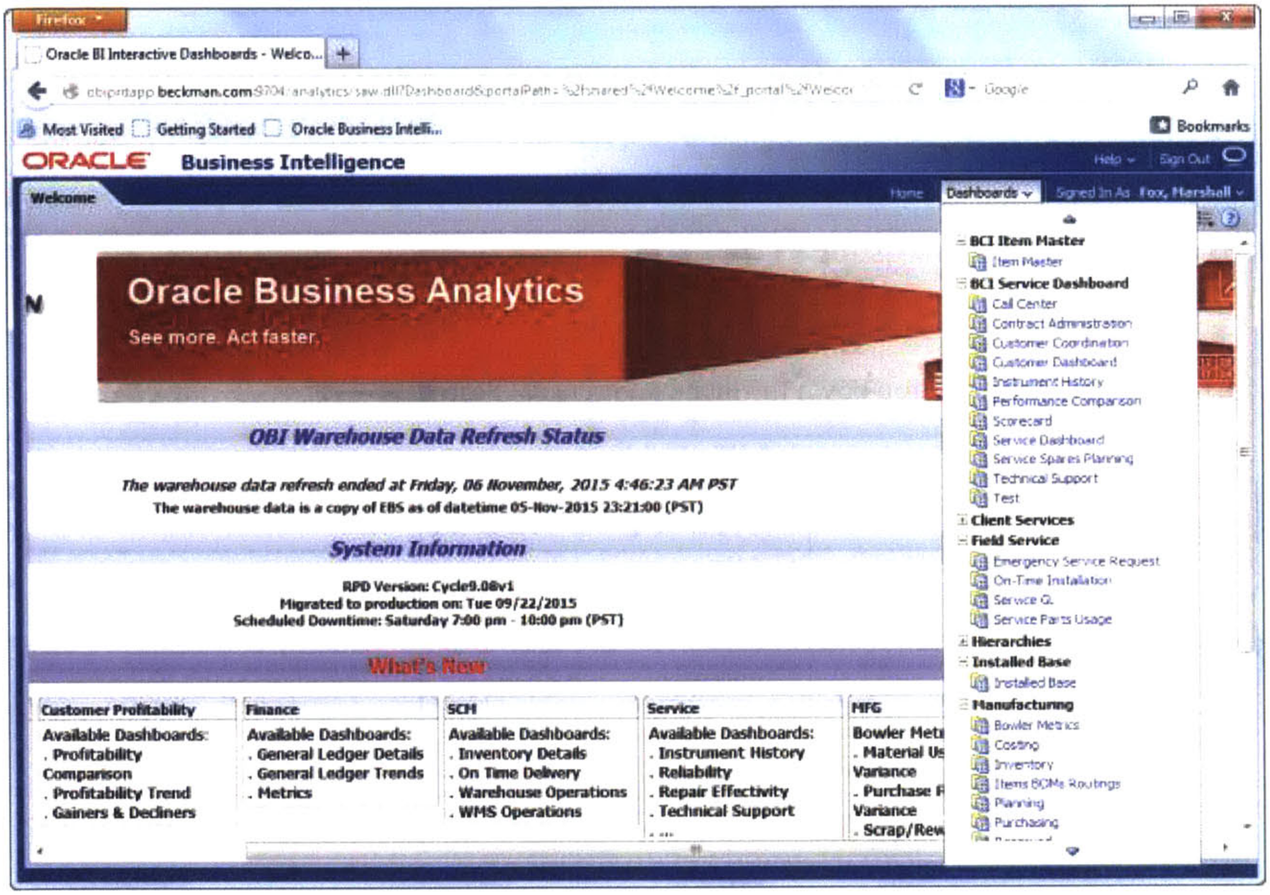


29.) Save and close the service record file and navigate back to the "Potential ESC Impact Calculation.xlsx" file.

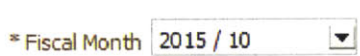
30.) Scroll to the right to enter the service record count into the appropriate month.

10.4 Using Oracle Business Intelligence to extract ESC Data

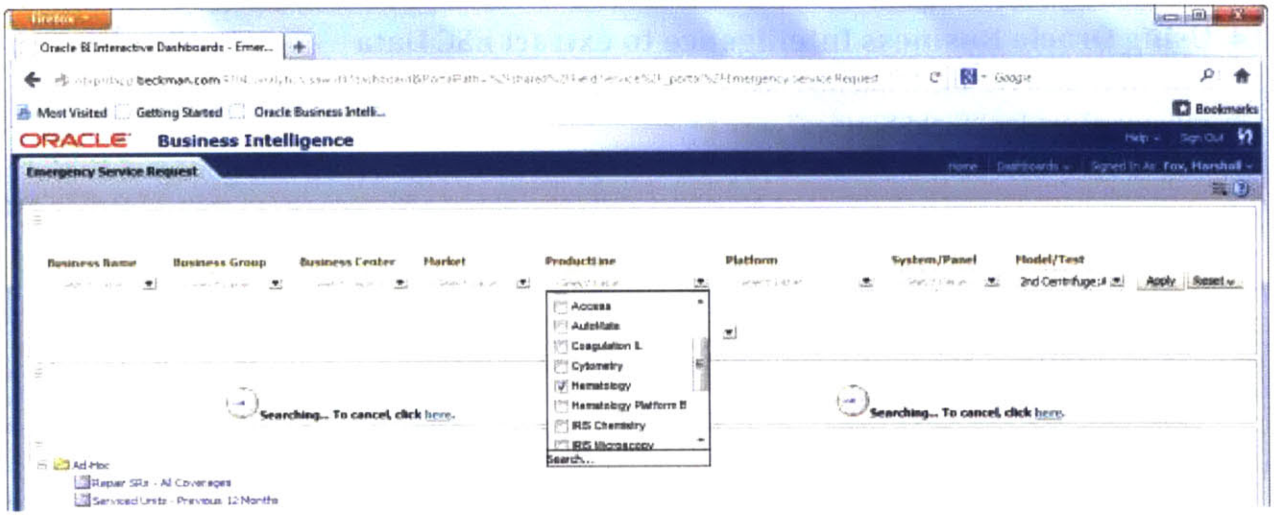
1.) Go to Oracle Business Intelligence. Open the Dashboard and click "Emergency Service Request" under "Field Service"



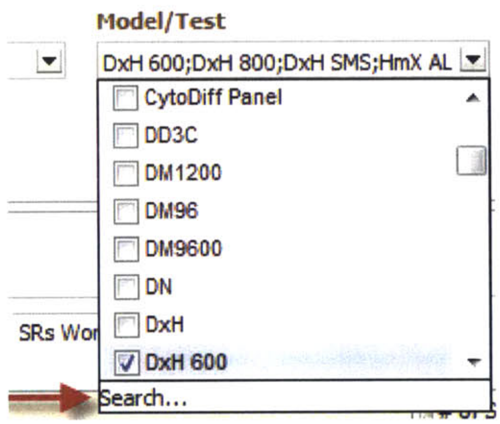
2.) Choose the desired "Fiscal Month." Note: If the fiscal month is not complete, you will only be able to pull partial data.

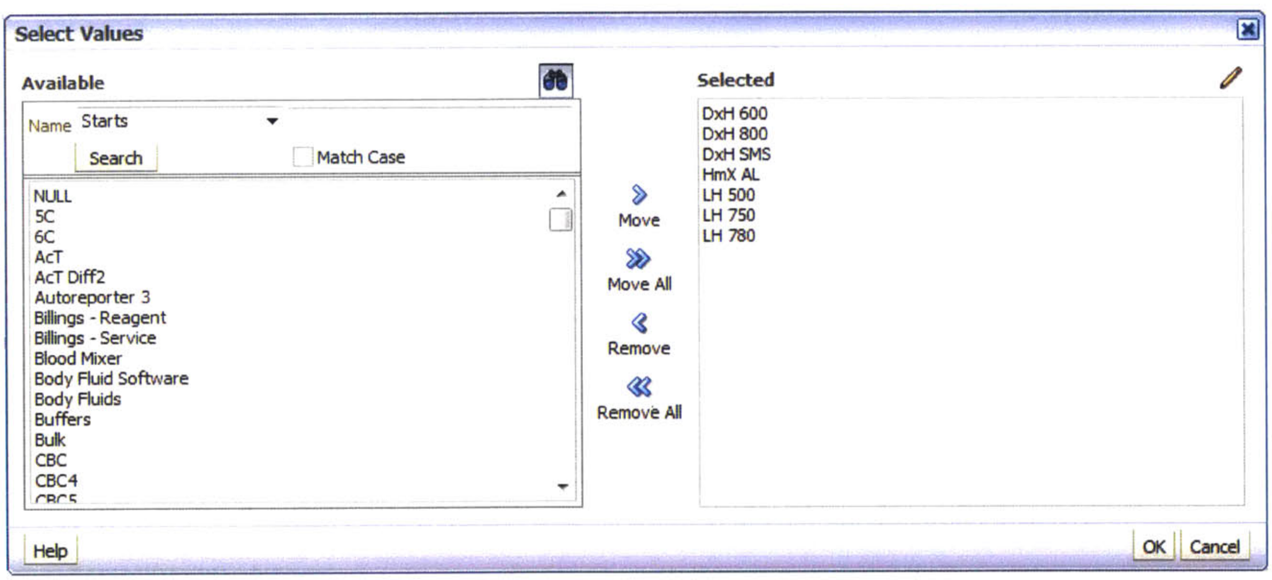


3.) Under Product Line, select the "Hematology"

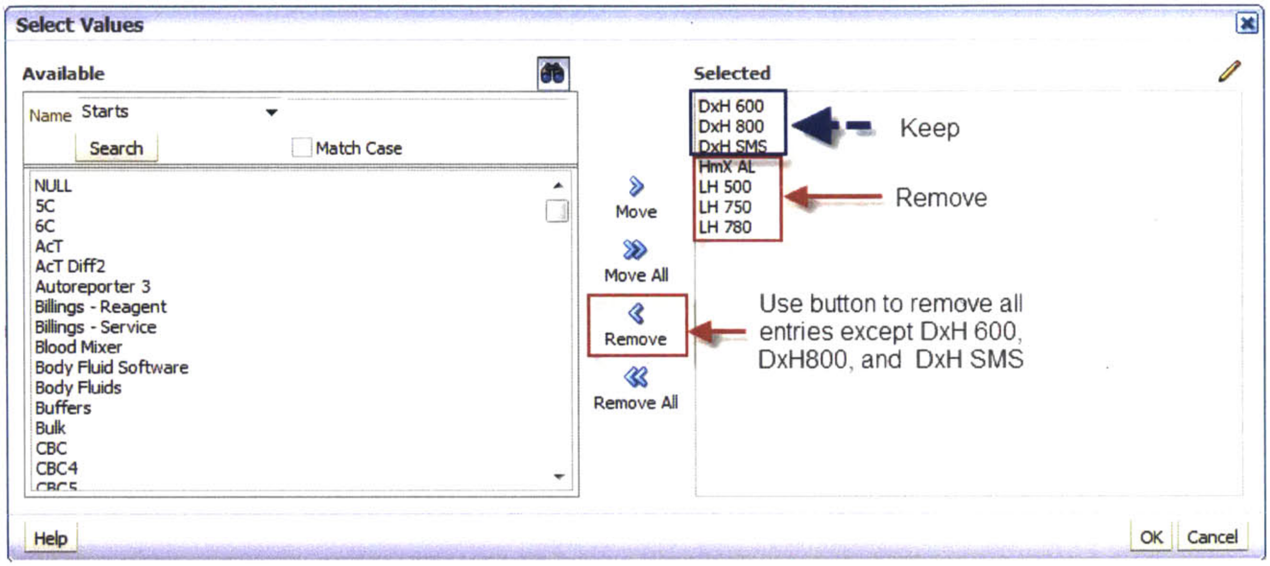


4.) Under Model/Test, drop down the menu and select, "Search…"

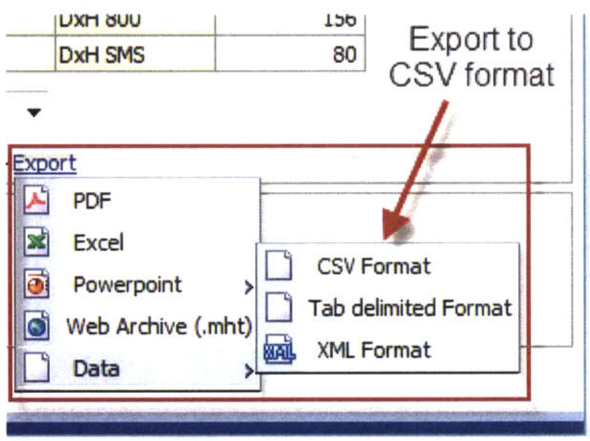




5.) Select all entries EXCEPT DxH600, DxH800, and DxH SMS and remove them from the right hand selected panel



6.) Click Ok
7.) Click "Apply" on the dashboard screen. After some time (could take 5-10 minutes), the in-month Warranty Data will become available for download along with a summary of the install base values.
8.) The install base can be found by summing up the Warranty Units Report on the LEFT side of the page.
9.) The service record data can be extracted by downloading the Warranty Repair SRs Report from the RIGHT side of the page by clicking "Export" -> "Data" -> "CSV Format"



10.) Save the file to your desktop (this could take several minutes).
11.) Open the file in excel and "save as" a .xlsx file using the naming convention "ESC SR Data [MM] – [Month] [YYYY] ESC.xlsx "Place the file in the L:\Reliability Engineering\PD L1 SPC\ESC Calculation folder

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