IMPROVEMENT OF STATISTICAL PROCESS CONTROL AT ST. JUDE MEDICAL'S

CARDIAC MANUFACTURING FACILITY

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ABSTRACT

Improvement of statistical process control at St. Jude Medical's cardiac rhythm management manufacturing facility.

By

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Sig sigma is a methodology where companies strive to reproduce results ending up having a 99.9996% chance their product will be void of defects. In order for companies to reach six sigma, statistical process control (SPC) needs to be introduced. SPC has many different tools associated with it, control charts being one of them. Control charts play a vital role in managing how a process is behaving. Control charts allow users to identify special causes, or shifts, and can therefore change the process to keep producing good products, free of defects.

There are many factories and manufacturing facilities having implemented some sort of statistical process control. St. Jude Medical implemented control charts to monitor different tools on the manufacturing line. How the data is entered and stored poses a difficult situation for the person monitoring the processes. The program used to keep the control charts is not user friendly and difficult to use. Another program can be produced to provide a greater level of efficiency.

The goals of this project are to stress how important control charts are in the manufacturing world, what problems are currently seen for operators and supervisors, and how a new and improved program can help fix the current situation. This paper goes into the reasons for the change as well has what has been improved.

ACKNOWLEDGMENTS

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LIST OF NOMENCLATURE

SPC   Statistical Process Control

UCL   Upper Control Limit

LCL   Lower Control Limit

SJM   Saint Jude Medical

X-BAR   Average of Data Set

R   Range of Data Set

CAPA   Corrective Action, Preventative Action

CHAPTER I: INTRODUCTION

1.1 SPC

Statistical process control (SPC) is a concept, which allows processes to be closely

monitored. Within manufacturing companies SPC is vital to maintain quality products, while at

the same time minimizing defects. Statistics is the central theme when looking at data, and SPC

revolves around different statistical methods. They are used to understand processes, determine

why those processes behave the way they do, and eventually learn to control them to limit

defects and improve the overall process.

1.2 HISTORY OF SPC AND CONTROL CHARTS

SPC is a relatively new idea, which is slowly being integrated in many manufacturing

facilities. There are currently nine "tools" that encompass SPC, which include flow charts, run

charts, Pareto charts and analysis, cause-and-effect diagrams, frequency histograms, control

charts, process capability studies, acceptance sampling plans, and scatter diagrams. [1] Of

these, control charts are among some of the most popular and easiest to understand. Control

charts are considered by some companies to be the exclusive tool of people on the production

floor, a tool that tells a machine operator, for example, when to adjust the machine and when not

to adjust the machine. [1] The control charts, also known as Shewhart control charts, were first

developed by Dr. Walter A. Shewhart. He worked on the charts prior to 1931, but 1931 is when

his book, *Economic Control of Quality of Manufactured Product*, was published describing these

charts. He was a member of the technical staff at Bell Telephone Laboratories in New York, and

at the time his book came out, many improvements were made in manufacturing industry.

In the past, pre-WWII, many of the consumer goods in the United States were of low quality. During WWII many of the manufacturing companies started to implement SPC in order to achieve high quality parts used for military. After WWII ended, the United States returned to its low quality manufacturing ways. Many of the programs used to monitor manufacturing degenerated into meaningless record-keeping exercises. [1] There are several reasons for the postwar deterioration including; people were intent on buying consumer goods regardless of quality, too much statistical-oriented tasks were perceived as too difficult to understand, SPC was looked as a technical tool designed only for quality control personnel, and lastly management did not see the importance behind SPC as a vital part of any business strategy or management's responsibility. The decline of SPC in the United States allowed other countries to get ahead with the production and distribution of consumer goods, mainly Japan.

Dr. W. Edwards Deming, a practicing statistician in Washington, D.C., taught statistical quality control methods to Japanese engineers and managers, beginning in 1950. [1] As the Japanese started to beat out the United States in areas including automotive and electrical goods, the United States started to worry. The United States eventually caught up, but not until the 1980's. During those thirty years, SPC started to integrate itself back into manufacturing processes nationwide, and currently can now be seen in many manufacturing companies. Among the nine different tools listed above, Shewhart, or control, charts are used the most often. It has been said, "If you do not use control charts in your process, you are not using SPC. If you use only control charts in your process, you are using SPC but not effectively." [1] Control charts are some of the more common ways of using SPC. Understanding the basis of how they function and what results they show can determine the success of a process.

1.3 CONTROL CHARTS

Control charts stem from the well known normal distribution curve. The normal distribution curve, also known as a bell curve, relies on the fact that a majority of data values fall within a certain distribution, known as standard deviations. Nearly 99.73% of all data values will fall within plus or minus three standard deviations. Taking the shape of the bell curve and turning it on its side, the basis of the control chart is formed.
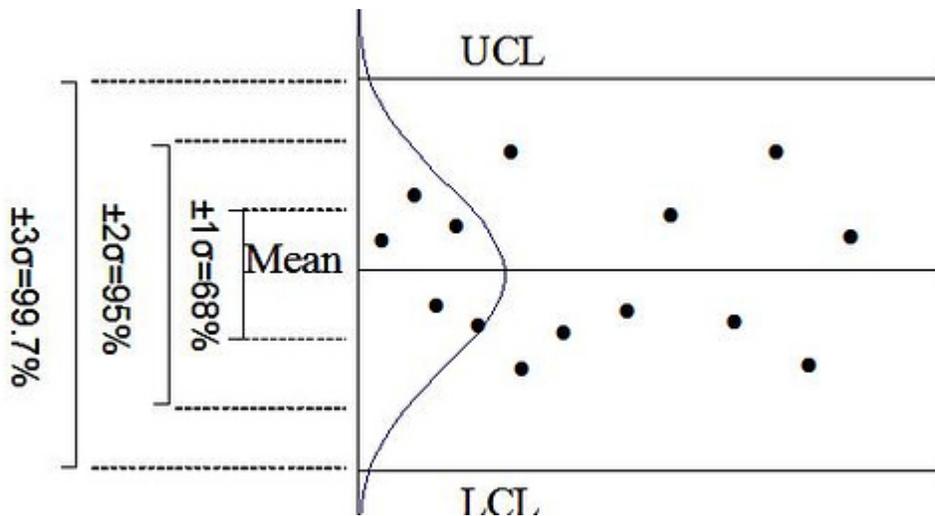
Figure 1: Normal distribution curve on its side representing the basis of a control chart. [2]

Control charts display data values, usually with time intervals increasing along the x-axis and the y-axis is for the units being measured. A control chart is broken into six sections, six separate sigma, or normal distribution, regions. After three sigma lengths away from the mean are limits, both an upper and a lower. The idea of normal distribution is the theoretical basis for the development of control charts. [1]

There are two different types of control charts, variable and attribute. Variable charts use measured data while attribute charts use counted data. In this paper variable charts will be

discussed. Two of the main types of variable charts are Xbar and R charts, which stand for average and range. Assuming there are samples of four taken daily, the Xbar chart will display the average while the range chart will display the difference between the largest data value and the smallest data value. These two charts can provide valuable data, which will aid in determining if a process is in control.
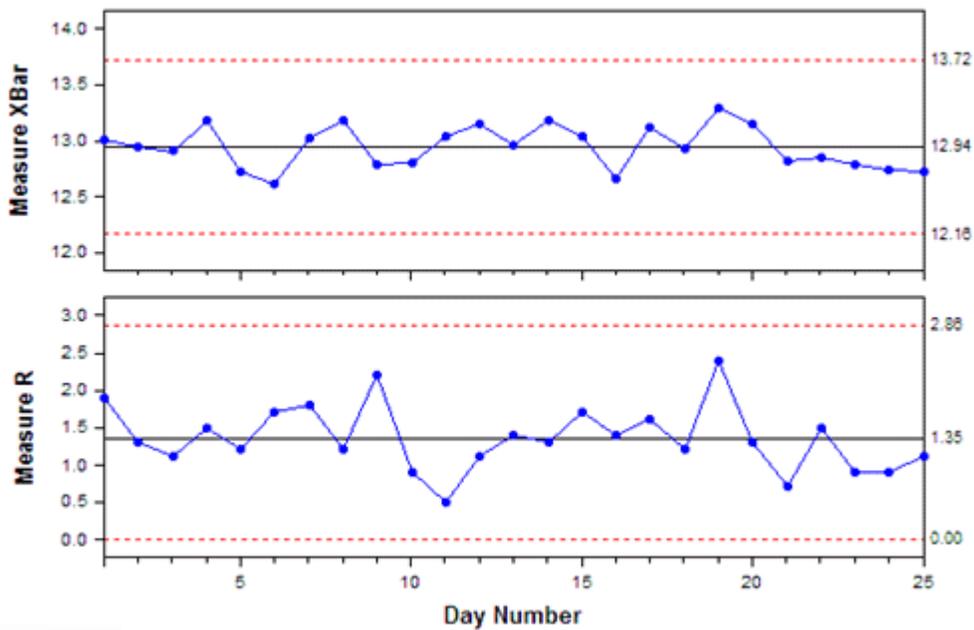
Figure 2: Examples of what Xbar and R control charts should look like over the course of a month. The red dashed lines indicate the upper and lower control limits, while the blue lines indicate the measured data. [3]

In order to set up these two charts data needs to be collected, the common data set should consist of 25 data values. [1] After enough data is collected, standard deviations can be calculated as well as upper and lower control limits for both the Xbar and R charts. Once the data has been collected, the X data will need to be averaged, as well as the R data. Using the following equations, the UCL_Xbar, LCL_Xbar, UCL_R and LCL_R can be calculated.

Xbar Chart: $\text{UCL} = \bar{\bar{X}} + A_2\bar{R}$ Range Chart: $\text{UCL} = D_4\bar{R}$

$\text{LCL} = \bar{\bar{X}} - A_2\bar{R}$ $\text{LCL} = D_3\bar{R}$

Table 1: Table of constants that help determine the UCL and LCL of the Xbar and Range chart.

[4]

Subgroup	X-bar chart		S-chart		R-chart	
	Using Ra	Using Sa				
n	A2	A3	B3	B4	D3	D4
2	1.886	2.659	0	3.267	0	3.268
3	1.023	1.954	0	2.568	0	2.574
4	0.729	1.628	0	2.266	0	2.282
5	0.577	1.427	0	2.089	0	2.114
6	0.483	1.287	0.03	1.97	0	2.004
7	0.419	1.182	0.118	1.882	0.076	1.924
8	0.373	1.099	0.185	1.815	0.136	1.864
9	0.337	1.032	0.239	1.761	0.184	1.816
10	0.308	0.975	0.284	1.716	0.223	1.777
11	0.285	0.927	0.322	1.678	0.256	1.744
12	0.266	0.886	0.354	1.646	0.283	1.717
13	0.249	0.85	0.382	1.619	0.307	1.693
14	0.235	0.817	0.407	1.593	0.328	1.672
15	0.223	0.789	0.428	1.572	0.347	1.653

Using Table 1 above and inserting the corresponding values into the formulas, one can

determine the UCL and LCL for the Xbar and R chart. All of the necessary quantities can be

found and monitoring of the charts can take place.

Control charts are one of the tools of SPC allowing users to monitor processes.

Depending on how the chart behaves, one can determine if certain processes are in control.

Knowing information about a process will lead to reduced variability. Reduced variability means more consistent performance and therefore enhances confidence in the product. [1] Similarly, reduced variability in manufactured goods means less scrap and rework. By closely monitoring control charts, one can spot any changes or problems, whether they are due to defective raw materials, breakdown or wear of machines, improperly trained personnel, uncalibrated instruments, or inconsistent management policies. [1] For the person who monitors control charts, there are criteria on what justifies an out of place data point, or special cause.

Throughout the emergence of control charts, many have built rules and regulations behind them, most notably how to determine when a process is out of control. There are currently four known rules which determine when a process is out of control, and they are Shewhart's single criterion, Western Electric's patterns (AT&T), L.S. Nelson's (adapted from AT&T), and A. H. Jaehn's zone control charts.

Shewhart's single criterion says when a data value goes outside of the control limits, either greater than the upper, or less than the lower, the process is no longer in control. While this is an easy way to determine if a process is out of control, it misses other trends that also demonstrate when a process is out of control.

Western Electric rules are much more complicated and require a very in depth view of the data. They split the control chart into six regions, each region containing a specific sigma away from the mean. Based on which region the data set falls into, certain rules govern if the process is in control.
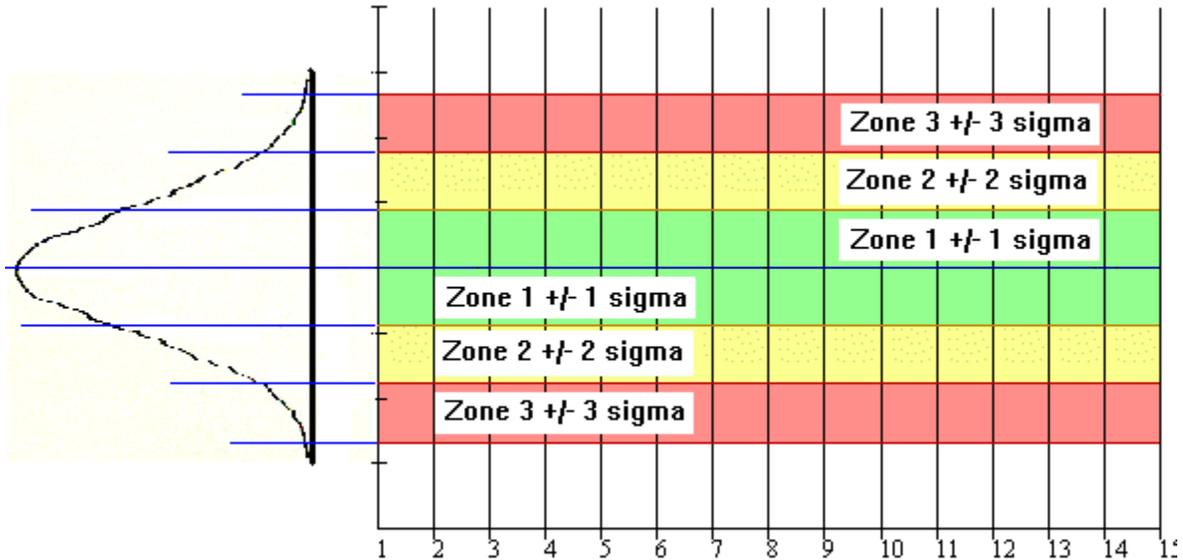
Figure 3: A control chart broken up into six different zones, where each zone signifies a different value. [5]

Rules for Western Electric Control Charts:

1. A single point beyond zone 3.

2. Two out of three points in zone 3, on the same side.

3. Four out of five points in zone 2, on the same side.

4. Eight points in a row in zone 1, on the same side.

5. Fifteen or more points in a row in zone 1, either side.

6. Eight points in a row on both sides of the center line but non falling in zone 1.

7. Systematic or cyclical patterns. (Ex: High, low, high, low...)

8. A long series of consecutive points going in the same direction. (Trending high, or trending low)

Within the Western Electric handbook there are six more patterns. Most practitioners of control charts tend not to use too many as the patterns start to become confusing.

One of the other rules are from L.S. Nelson. Nelson's are very similar to those of Western Electrics, and vary only slightly.

Jaehn's zone control chart is very unique. Each zone corresponds to a different value; beyond zone 3 is 8 points, zone 3 is 4 points, zone 2 is 2 points, zone 1 is 1 point and the center line is zero points. As data is collected a running total of points is tallied. When data points add up to 8 or more then the process is out of control.

Most companies tend to keep their criteria in a safe balance where they will have enough to notice any changes, but not too many making control charts to laborious to keep and too intense to understand. A good rule of thumb is to monitor for any points outside of zone 3, and runs where 8 points occur on one side of the center line, a trend where 5-6 points continue to either increase or decrease, and if two continuous points are just in a control limit.

1.4 REASONS FOR CONTROL

Variability in a process is directly related to the materials used, machines, people, methods, environment, and management. [1] There are many reasons as to why a process will become out of control. In many manufacturing companies, understanding where the problem is can save a company thousands of dollars. The most noticeable costs from having an out of control process are reworks and scraped components. These are the main two costs most people think of, however there are also many other costs involved due to manufacturing testing, which include cost of sampling, measuring, recording, plotting, data handling, time, personnel training, access to equipment, and logistics. When a process is not controlled problems will occur with

the product and end up affecting the company far worse than if it spent the time and energy to monitor processes. The cost of not detecting a shift in the process will cause other problems including poor yield, more reworks, increased waste, 100% inspection, downtime for machines, and increased labor. Not only does the manufacturing facility suffer so does the customer due to a decrease in customer satisfaction, goodwill, more returned products, more replacements, and liability. [1] The use of control charts becomes a vital component of a successful business and cannot be emphasized enough how important their role is.

1.5 ST. JUDE MEDICAL

Manufacturing facilities, such as the St. Jude Medical's Cardiac Rhythm Management Division located in Sylmar, CA, have control charts monitoring many different tools and machines. They rely on good statistical data to monitor processes. SJM builds cardiac leads and pacers at this facility, and leads account for much of their manufacturing product. There are high voltage and low voltage leads, both having similar manufacturing operations. Their product requires certain components to be either welded or crimped. Due to the machining process, not all welds or crimps are going to behave the same. There are numerous factors that come into play when determining how strong a weld or crimp is; for example, the raw material used, the experience of the operator, how the parts are tested for strength, etc. Their control charts attempt to monitor the weld and crimp strength on a daily basis to note any special causes or changes in the process. There are tensile tests done multiple times throughout the day for each welder and crimper. Tests are conducted at the beginning and end of each shift. There are usually two shifts during the day, allowing for four data points per machine per day. Data collected from the operators are piled into Excel spreadsheets on one central computer. Each welder and crimper has a corresponding tool number which relates to a single Excel file. There are multiple Excel

files and within each Excel file are multiple tabs. Four tabs for every month where each tab has

its own purpose. Two tabs are for data entry (data collected and disposition) and the other two

tabs display the X-bar chart and the R chart. Figure 4 depicts what a sample spreadsheet looks

like.
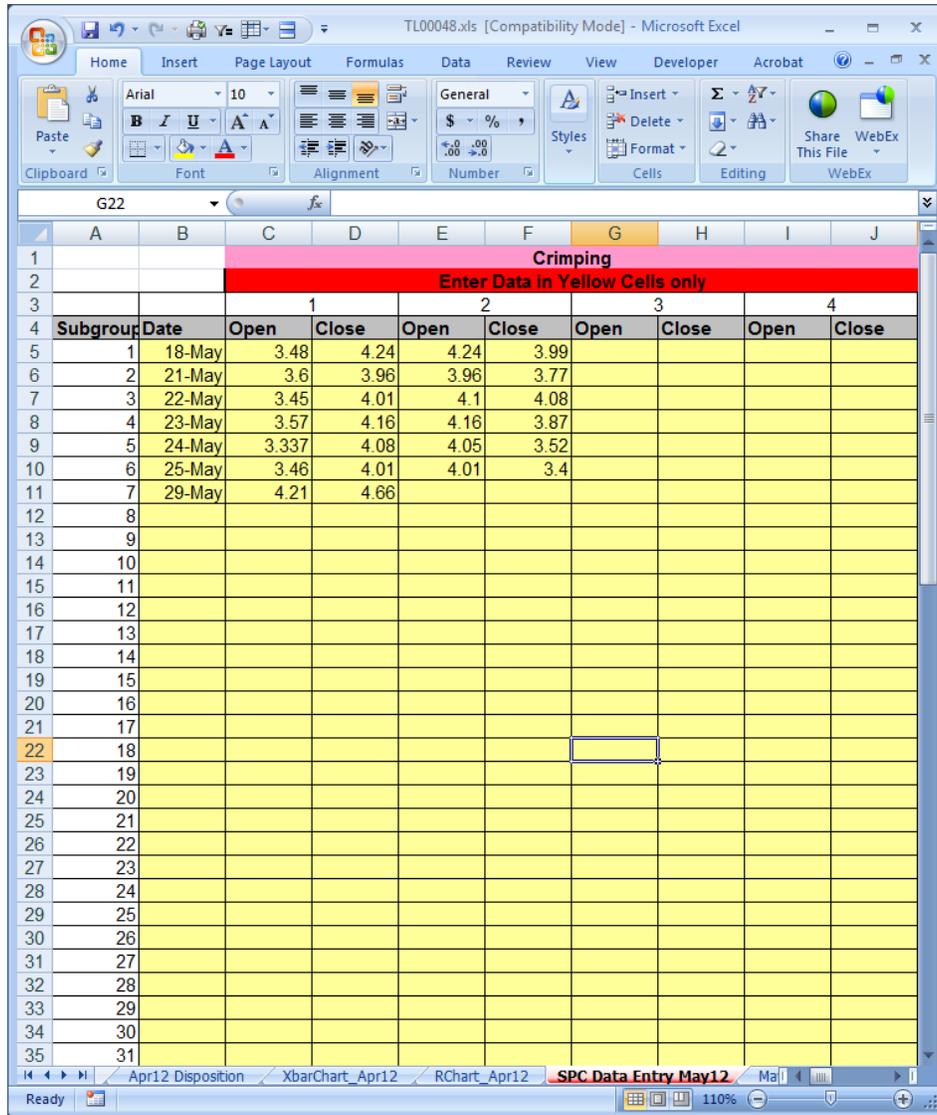
Figure 4: The opening view of most of the spreadsheets. What cannot be seen in this image is

the many others rows and columns depicting values for determining range, average, upper and

lower limits.

One of the main concerns with having so many different Excel files and different tabs is that data was being incorrectly inserted into wrong sections. There would be numerous times during the course of a week where data would be located in an incorrect section, or the data would be formatted incorrectly. With so many different tables to look at, searching through the data each day made monitoring the charts and tables very time consuming. Due to Excel's formatting, data inserted would sometimes be mistaken for dates instead of values (i.e. 3.14 ended up being March 14), and lastly making new tabs each month was a labor intensive process.

Another problem occurred once a month during "Corrective Action/Preventative Action" (CAPA) meetings. These meetings are intended to go through the processes and determine if they are still in control. If a process is no longer in control then an engineering group would decide what to do. At the CAPA meetings the control charts are presented with the previous month's data. Depending on the data, action would be taken to correct any special causes. Pooling together data from the Excel files would be intense and often times one would notice points to be out of the control limits. During the meeting the group would want to know why the process was out of control. In order to determine the cause, research needs to be conducted and an explanation or correction needed to be determined. Many times an operator would insert the data and the data point would be well out of the control limits, however without close monitoring of all the Excel files the outliers would normally be overlooked until the CAPA presentation. When out of specification points are found, the person who manages the control charts has to figure out what occurred on that specific day. There is another program, besides Excel, where the operators have to insert data collected from tensile tests of welds and crimps. This program can only be accessed by supervisors, so when a point is out of the control limits they are the ones having to spend precious time searching for the specific day when the questionable data was

entered. Being able to fix these factors would help save operators, engineers, and floor supervisors time and reduce stress.

In the manufacturing world there are seven deadly wastes, which include overproduction, inventory, waiting, transportation, processing, motion, and defects. [6] Of the seven mentioned, waiting, processing, motion, and defects all contributed due to the inadequate control chart system. Waiting due to having people wait to insert data on the one computer, processing due to operators having to insert data in multiple times, and often times the data is entered incorrectly making supervisors locate the wrongly inserted data, motion from having supervisors and trainers locate operators to ask them about the data, and defects due to changing out welder components and/or crimpers based on misleading data.

CHAPTER II: OBJECTIVES

There are many objectives in for improving the current system.

1. Construct a layout where operators can easily insert data.

2. Build a template involving all welders and crimpers on the low voltage floor.

3. Decrease the number of Excel files, as well as decrease the number of tabs.

4. Allow for CAPA reports to be easily generated each month.

5. Implement an ability to double check for points outside of the control limits.

6. Have both the X-bar and R chart on one screen instead of two tabs.

7. Allow for automatic email notification of supervisors when points are out of control.

8. At the end of every month have the data sent to separate Excel files.

9. Install time stamps for when data is entered.

10. Manage database so only authorized users can change the layout.

11. Allow operators to input data, and restrict deletion.

12. Allow operators to insert data points and monitor the graphs on the same screen.

CHAPTER III: METHODS

The idea of building a six-sigma environment is what most companies strive for. In order to achieve this goal companies have continuous improvement programs. Mistake proofing and lean engineering are programs which help understand how a manufacturing floor should operate. Using ideas such as eliminating non-value added activities, limiting the seven deadly wastes, and noticing the 5 S's (Sort, shine/scrub, set in order, standardize, and sustain) [6] a program was designed allowing for the operators to better use and monitor control charts, as well as being able to notify administrators where and when a process becomes out of control. With high throughput of product, any downtime of a machine becomes a large bottleneck. The major thought behind the new control chart system took this into consideration.

Understanding most people are familiar with Excel, the desire was to mimic Excel and its functions. The program used to do this is called FileMaker Pro (FileMaker, Inc.). Using FileMaker Pro allows users to build custom layouts and gives the user complete freedom in how data is managed and viewed. Since the past way to insert and monitor data used over twenty different Excel files, this seemed like a reasonable approach. FileMaker also has the ability to make layouts identical to Excel, so switching software would not be difficult.

The layout of the program begins with a home screen allowing for the user to choose which tool number they would like to insert data for, as can be seen in figure 5.

ST. JUDE MEDICAL™
MORE CONTROL. LESS RISK.

60010158	60013867	60020096	60020098
TL00022 - 60010158	TL00031 - 60013867	TL00030 - 60020096	TL00051 - 60020098
TL00047 - 60010158	TL00052 - 60013867	TL00048 - 60020096	
TL00079 - 60010158			
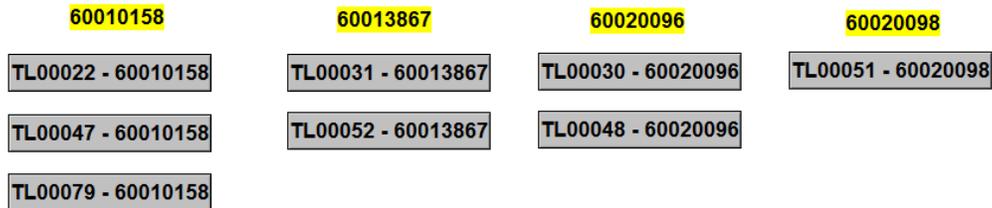
Figure 5: A visual of the home screen for a few of the low voltage crimpers and welders.

Since most operators are familiar with their respective tool, each tool falls under the specific crimper or welder. After determining which crimper they have, they click on the specific tooling number. The initial eight seen in figure 5 accounts for just less than half of the possible crimpers and welders. At the time when this program was made there were 21 different types of crimpers and welders and of those 21, only eight were being monitored.

After clicking on a tooling number's grey button, the operator would be sent to another screen, which corresponds to the correct tool, figure 6.

St. Jude Medical™
MORE CONTROL. LESS RISK.

Insert pull test data according to your shift. (Shift 1 or Shift 2)
When finished inputting data, click the yellow "FINISH" button.
Important: If a box appears after hitting "FINISH", hit allow.

Date
5/29/2012

Pull Spec
3

Shift 1		Shift 2	
User1		User2	
Open 1		Open 3	
Close 1		Close 3	
Open 2		Open 4	
Close 2		Close 4	

Finish

Figure 6: The layout for where data is entered. Each tool has a nearly identical layout.

Figure 6 displays the following information: Shift #1 or Shift #2, User1 and User2's name, Open or Close, the current date, the minimum pull specification, and a brief instuction section aiding new operators, or assisting those operators which may have forgot what to do. Each place where the operator can enter data is known as a field, and fields are what drive this system. A field represents one data value in the form of a name, date, number, etc.

The reason why there are two open and two close fields is because when there happens to be an incorrectly pulled sample, the operator will have to conduct another pull test. The floor supervisor suggested this in order to not exclude any data, as operators would often use incorrect pull fixtures.

At SJM operators test the pull strength of either the weld or crimp at the beginning of the shift (open) and once more at the end (close). After the operator inserts the data in the correct field they hit the yellow finish button. Using the bright finish button concludes their data entry

and inputs the data into a wide variety of equations. These equations build the charts, as well as detects for out of spec points. The equations can be found in Appendix A. Besides inputting and checking for out of spec points, hitting the finish button also runs scripts.

Scripts are special to FileMaker, and they are a functions which allows multiple operations to perform automatically. Each script must be programmed by the user, but once programmed it allows for computing to take place with ease. The scripts used can be found in Appendix B.

There are six different scripts performing a wide variety of tasks.

- "Email Notification" will automatically double check the operator's inputted value against the current specification as well as the upper and lower control limit values. If the inputted value is above the upper limit or below either the lower limit or specification an email will be sent to any user wanting to be kept aware. For example, quality engineers, the floor supervisor, the lead operator, the floor technician, and the manager can all be notified if a crimper or welder has a special cause value.

- "Export Into Excel" automatically sends all the data from the current tool number into an Excel file. This feature was added for Excel's graphing capability and for those users who would rather see the data in rows and columns. There is another feature within this script, field export order, that allows for the exported data to be organized in a customized fashion. FileMaker Pro lacked in graph making abilities when this program was written, however they plan to increase customizing graphs. At the end of each month all of the data will be exported into a separate folder with a .xls file type.

- "Go to home menu_All" returns the operator to the home menu. Due to the fact each tooling number has its own data set, each script had to be written individually. This script is a global script meaning all tooling layouts use this to return to the home menu.

- "Finish_##" performs all of the three scripts above simultaneously. When the operator hits the finish button the program looks for out of spec points, exports the data into a .xls file type (if at the end of the month), and lastly returns to the home menu.

- "New Record TL000##" creates a new record for the operator to insert data on. This was created in order to save time and hassle when creating new records. In order to keep the program as simple as possible automatic operations were created. At the layout of all the different tooling number buttons, figure 5, when the operator clicks the button a new record will be created only when the current date does not match the date of data input.

- "Date Counter Global" is another global script that updates the current day. All of the layouts compare their date to the global date. When the two do not match a new record will be created, and if the global date is the last date in the month the data will be exported into another folder having .xls file types.

Once the finish button has been clicked, the layout will automatically return to the home page with all of the other welding and crimping tooling numbers. If the data value was out of spec another window appears notifying the operator an email will be sent, then the home screen appears.

Depending on the amount of data inserted each day the upper and lower control limit values varied. Some days not all welders or crimpers would be used, and so equations were made to calculate the changing control limits based on the number of data entries, appendix A. Screenshots of the different fields and scripts can be seen in appendix C.

CHAPTER IV: RESULTS

The new program allows for operators to insert data quicker and with better accuracy. Due to FileMaker's restraints, each field can be programmed to represent a name, number, date, etc. There is no longer a chance for operators to enter numbers and have the computer define them as dates. Less mistakes are made due to fewer Excel files and tabs as well. With one main home page, and many tables incorporated into one large file, there is no need to have multiple Excel files resulting in fewer chances to make a mistake.

There is an increased awareness of how the welders and crimpers behave due to easier vision of control charts. Having control charts on the same page where the data is being inserted allows operators to follow the behavior of their machines by scrolling down the page.

Supervisors are able to receive notifications when the data is beyond either the upper or lower control limits. An automatic email notification is a great tool to have as it gives an immediate update on how the processes are behaving. In order to use this feature an administrator will need to change a few script options, which may be difficult if they are not familiar with FileMaker.

The X-bar chart and R chart behave just as they would using the previous Excel spreadsheets. Exporting the data into an Excel spreadsheet at the end of each month was successful. Using the FileMaker Pro template created also allows other manufacturing areas to use the control charts if desired.

Reducing many different Excel files into one FileMaker Pro file was of extreme importance as it helped reduce wait times, due to waiting for Excel files to open and close. Not only does decreasing the number of files help the operators, but it also helps the person who is

managing the control charts. Instead of painstakingly going through the masses of tabs to locate data on a tool, one can easily sort through the FileMaker file.

Due to the fact control charts do not control anything, and are merely a tool for providing data that can be used for managing processes the only approval needed to implement the FileMaker Pro program would come from management. [1] The main concern from the floor supervisor included whether or not the operators would be able to use the program, and if it would negatively affect the input of data. Also, since control charts are a tool used to manage data, quality engineers would not need to be involved in implementation. Control charts are monitored by those who use them, so it is up to the discretion of the end user (i.e. the operators and those on the manufacturing floor). Basic equations in the FileMaker Pro program were similar to those used in the previous Excel files so there was no large difference with how the data was calculated. The major changes had to do with how the data was inserted, how it was viewed, what occurs during a special cause moment, efficiency of data insertion, and the overall effectiveness of monitoring control charts during a course of a month until the next CAPA meeting.

The original FileMaker file was built using a demo version. During the span of four months there were countless changes made from the floor supervisor. The floor supervisor believed strongly in making the control charts as simple as possible, due to the fact there were many problems at the time. SPC was not used on the low voltage floor until about the beginning of 2011, so the Excel files were the first type of monitoring tool used. Due to the nature of change with an existing process, the current FileMaker file is still being critiqued.

CHAPTER V: DISCUSSION

The objectives were met, however the floor supervisor thought some to be unnecessary. Having a security prompt to monitor who is allowed to access the data was unnecessary. There was no need to have a Username/Password prompt when opening the file, due to the confusion it might bring on operators as well as the technical team. However, after trying the security login a new feature was added. After users entered data there is an option, which prohibits altering the data after submitting the data and returning to the home menu. In order to change the data an operator would have to notify an administrator to manually change a value. Implementing this program saves tremendous amounts of time for the operators as they can access all their files within one main file, rather than trying to access twenty different files and searching for the right tab.

SPC is a collection of tools, mostly statistical, which help us to understand what is going on in any process that generates products, services, or information. [1] More specifically, control charts are one of the tools in today's manufacturing world that provides insight into how processes are operating. Valuable information can be presented using control charts, however control charts will not fix any process. The supervisors and operators must be aware of these control charts and be able to understand them. Trends, runs, groups, bunches, freaks are terms used by statisticians describing how a process is behaving. When it comes down to good manufacturing practices, those who are monitoring the control charts need to be able to recognize these patterns. By implementing a new and improved system, from visual clarity, to ease of data input, and auto notifying changes to supervisors all help in controlling processes that effect the end consumer product.

In the end, the final product is what matters and what drives company profits. Control charts aid in providing high throughput and therefore increased revenue. There are many factors when considering how the final product is produced from the raw materials, personnel, machines, etc. and knowing how these factors are interacting will allow management to decide the company goals. The control chart can be used to detect changes between machines, or between operators, or between lines, or between shifts, or between batches. [1] Detecting changes is far different than fixing the problems. Control charts do not control anything. They are merely tools for providing data that can be used for managing processes and, as such, should be looked on as management decision-making tools. [1] In today's capitalistic society manufacturing good product is necessary if one wants to be competitive, and having good control over processes allow this to happen.

Future work includes more code within the program, which would allow for more pattern recognition. The first program notices a point when it goes beyond a control limit and has the ability to email any supervisors. A next iteration would be to write more code that would detect trends, runs, bunches, etc. over numerous days. One of the main problems with control charts is when a user is trying to keep track of too many rules simultaneously. The user will either notice everything and assume the process is out of control, or vice versa, the user will become overwhelmed and miss certain special events that would normally alarm someone who is looking for the specific pattern. Integrating more code into the program would help the user to choose whether or not certain patterns should cause for action to be taken. Action normally consists of four kinds, resample the data, adjust the process mean, look for a special cause, or do nothing. Having multiple people monitor control charts would help, however that would be a waste according to the seven deadly wastes, processing.

Another future idea would be to put the program onto the SJM server so anyone who is interested can take a look at the processes. This would entail buying another version of the program and adjusting some of the parameters to allow others to view and not overwrite data.

Control charts use statistics to show how a process is behaving. Every process will have data associated with it and a control chart can be made. At SJM welders and crimpers are monitored, however there are many more processes occurring on the manufacturing floor. There is a possibility to write more programs that can monitor how operators are performing, which operating procedures are causing the most scrap or rework, at what times during the day is production peaking, etc. Knowing this sort of information would allow managers to make decisions towards manufacturing, and help them achieve a six-sigma environment.

CHAPTER 6: FUTURE WORK

There are many different ways of interpreting control charts, many mentioned earlier. An ideal program would be able to track every type of trend, run, clusters, special causes, etc. The capabilities of FileMaker are only as great as the person who writes the program. With more time and more knowledge a better program can be written. Knowing exactly how a control chart is behaving will give managers a perfect representation of how their tools or machines are behaving.

Producing a how to manual would be ideal, as most of the processes at SJM have a protocol to follow. Introducing a program manual would be beneficial for all those users left to come wondering why things were done the way they were.

More input from the operators and managers would help greatly as well, as they are the ones who will be directly involved in the future. During the trial versions of FileMaker, most of the ideas came from thin air and as the program progressed more input came from upper management. Customization makes FileMaker an ideal candidate for SPC and having more input from management would produce an even better program.

Lastly, the graphs were not as customizable as hoped for. Excel still produces bolder graphs, ones that are easier to interpret. Either FileMaker needs to update their software, or the exportation to Excel still needs to continue. Ideally, the best program would be able to do all of the tasks required to produce consistent results.

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APPENDIX A: EQUATIONS

This appendix contains the code written for each field.

Calc_rbarhigh_1 = If (Data Points_1=2; rbar2; If (Data Points_1=3; rbar3; If (Data

Points_1=4; rbar4; If (Data Points_1=5; rbar5; If (Data

Points_1=6; rbar6; If (Data Points_1=7; rbar7; If (Data

Points_1=8; rbar8;0)))))))

Calc_xbar_1 = If (Data Points_1=2; xbar2; If (Data Points_1=3; xbar3; If (Data

Points_1=4; xbar4; If (Data Points_1=5; xbar5; If (Data

Points_1=6; xbar6; If (Data Points_1=7; xbar7; If (Data

Points_1=8; xbar8;0)))))))

Data Points_1 = Count (Open 1;Open 2;Open 3;Open 4;Close 1;Close 2;Close

3;Close 4)

UCL_rbar_1 = Rbar * Calc_rbarhigh_1

LCL_rbar_1 = 0

UCL_xbar_1 = XDoubleBar + Calc_xbar_1 * Rbar

LCL_xbar_1 = XDoubleBar - Calc_xbar_1 * Rbar

R_1 = If (Data Points_1=0; 0; Max (Open 1;Open 2;Open 3;Open

4;Close 1;Close 2;Close 3;Close 4)-Min (Open 1;Open 2;Open

3;Open 4;Close 1;Close 2;Close 3;Close 4))

Xbar_1 = Average (Open 1;Open 2;Open 3;Open 4;Close 1;Close 2;Close 3;Close 4)

XDoubleBar and Rbar are values from the previous records, usually from at least 25 samples.

Pull Spec is determined by the product specifications.

rbar2 - rbar 8 can be found in Table 1.

xbar2 - xbar 8 can be found in Table 1.

This appendix contains the scripts functions.

Email Notification:

Script Name: [Email Notification_22]

```
↕ If [TL00022::Data Points_1 ≥ 2]
↕   If [TL00022::Xbar_1 < TL00022::LCL_xbar_1 or TL00022::Xbar_1 > TL00022::UCL_xbar_1 or (Min ( TL00022::Open 1; TL00022::Open 2; TL00022::Open 3; TL00022::Open 4; TL00022
↕     Send Mail [Send via E-mail Client; No dialog; To: "cedwards03@sjm.com"; Subject: "Out of Spec Crimper-TL00022"; Message: "Test showed xbar value out of range from UCL/LCL."]
↕   End If
↕ End If
```

Portion that is cutoff:

TL00022::Xbar_1 < TL00022::LCL_xbar_1 or TL00022::Xbar_1 >

TL00022::UCL_xbar_1 or (Min (TL00022::Open 1; TL00022::Open 2; TL00022::Open

3; TL00022::Open 4; TL00022::Close 1; TL00022::Close 2; TL00022::Close 3;

TL00022::Close 4) < TL00022::Pull Spec)

Export Into Excel:

Script Name: [Export Into Excel_22]

```
↕ If [SPCLeadsFinal::Date = Date ( Get ( CurrentDate )-1; 1; Get ( CurrentDate ))]
↕   Export Records [No dialog; "TL00022_date.xls"; Unicode (UTF-16)]
↕   Delete All Records [No dialog]
↕ End If
```

Go to home menu_All:

Script Name: [Go to home menu_All]

```
↕ Go to Layout ["Date Counter" (SPCLeadsFinal)]
```

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Finish_##:


```
Script Name:  Finish_22

  ↕ Perform Script ["Email Notification_22"]
  ↕ Perform Script ["Export Into Excel_22"]
  ↕ Perform Script ["Go to home menu_All"]
```

New Record TL000##:


```
Script Name:  New Record TL00022

  ↕ Go to Layout ["TL00022" (TL00022)]
  ↕ If [TL00022::Date ≠ Get ( CurrentDate )]
  ↕     New Record/Request
  ↕ End If
```
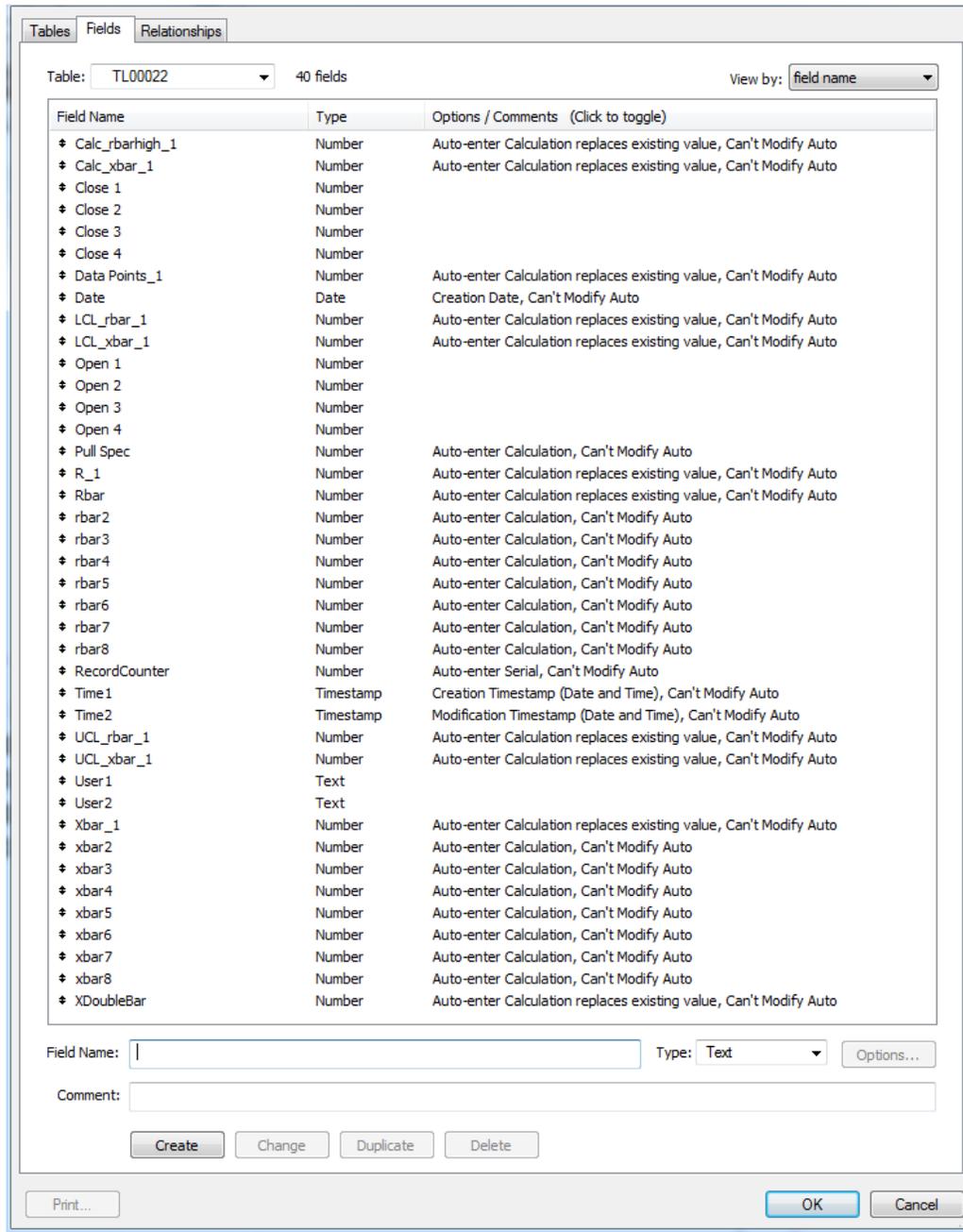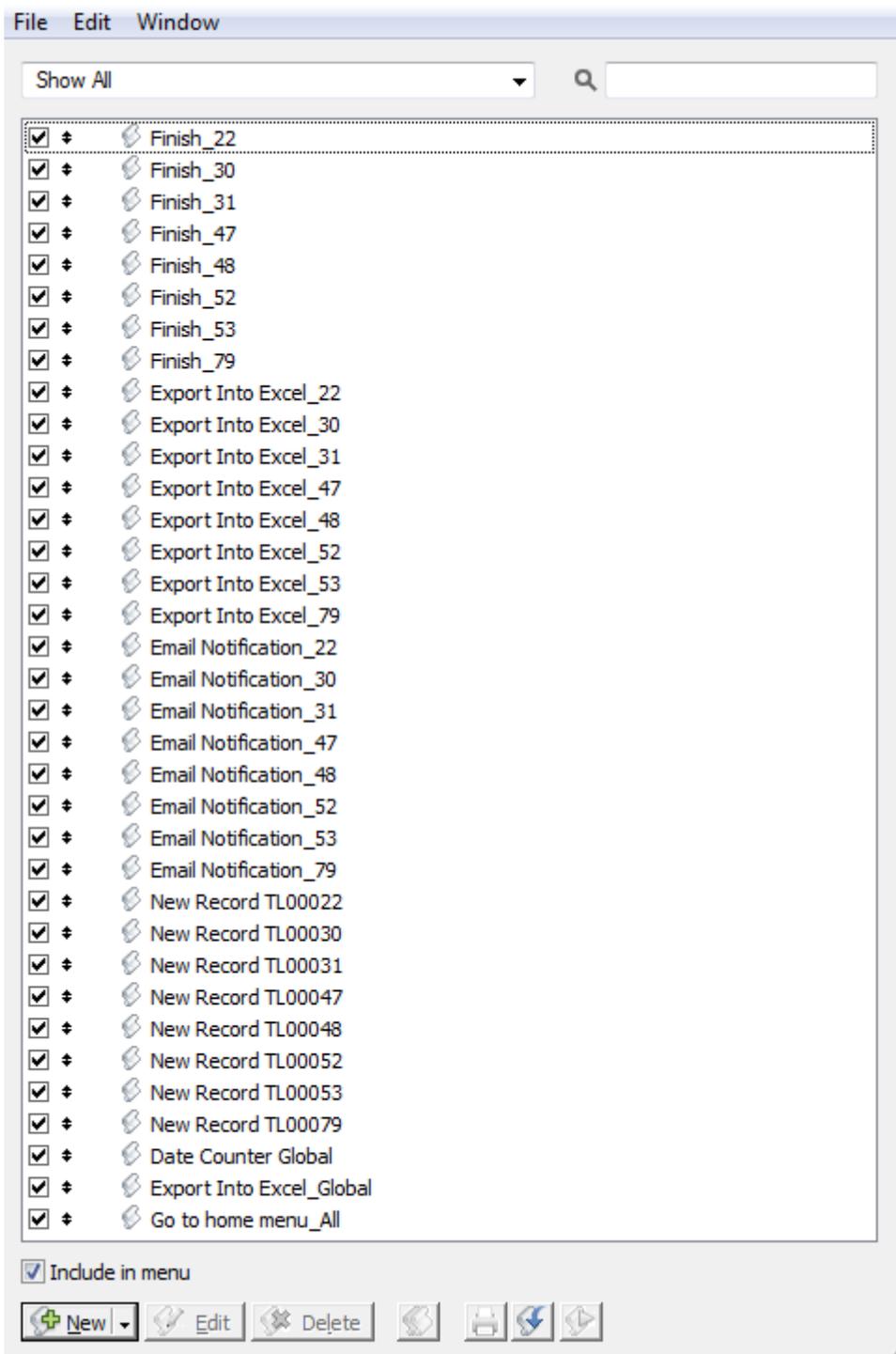
Date Counter Global:


```
Script Name:  Date Counter Global

  ↕ If [Get ( CurrentDate ) ≠ SPCLeadsFinal::Date]
  ↕     New Record/Request
  ↕ End If
  ↕ Go to Layout ["SPC_Sylmar" (SPCLeadsFinal)]
```

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APPENDIX C: SCREENSHOTS OF FILEMAKER

This appendix contains a few sample images of how FileMaker keeps track of different fields

and scripts used.

File   Edit   Window

Show All   ▼   🔍

☑ ↕   📎 Finish_22
☑ ↕   📎 Finish_30
☑ ↕   📎 Finish_31
☑ ↕   📎 Finish_47
☑ ↕   📎 Finish_48
☑ ↕   📎 Finish_52
☑ ↕   📎 Finish_53
☑ ↕   📎 Finish_79
☑ ↕   📎 Export Into Excel_22
☑ ↕   📎 Export Into Excel_30
☑ ↕   📎 Export Into Excel_31
☑ ↕   📎 Export Into Excel_47
☑ ↕   📎 Export Into Excel_48
☑ ↕   📎 Export Into Excel_52
☑ ↕   📎 Export Into Excel_53
☑ ↕   📎 Export Into Excel_79
☑ ↕   📎 Email Notification_22
☑ ↕   📎 Email Notification_30
☑ ↕   📎 Email Notification_31
☑ ↕   📎 Email Notification_47
☑ ↕   📎 Email Notification_48
☑ ↕   📎 Email Notification_52
☑ ↕   📎 Email Notification_53
☑ ↕   📎 Email Notification_79
☑ ↕   📎 New Record TL00022
☑ ↕   📎 New Record TL00030
☑ ↕   📎 New Record TL00031
☑ ↕   📎 New Record TL00047
☑ ↕   📎 New Record TL00048
☑ ↕   📎 New Record TL00052
☑ ↕   📎 New Record TL00053
☑ ↕   📎 New Record TL00079
☑ ↕   📎 Date Counter Global
☑ ↕   📎 Export Into Excel_Global
☑ ↕   📎 Go to home menu_All

☑ Include in menu

🟢 New ▾ │ 🖊 Edit │ ✖ Delete │ 📎 │ 🖨 📎 📎

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Select and move the fields to be exported. If you want to group data, add them to the 'Group by' list before moving the other fields.

Current Table ("TL00022") ▼

Calc_rbarhigh_1	
Calc_xbar_1	
Close 1	
Close 2	
Close 3	
Close 4	
Data Points_1	
Date	
LCL_rbar_1	
LCL_xbar_1	
Open 1	
Open 2	
Open 3	
Open 4	
Pull Spec	

Group By

Clear

Move

Move All

Clear All

Group by

Field export order

⇕ TL00052::Date
⇕ TL00052::Pull Spec
⇕ TL00052::XDoubleBar
⇕ TL00052::Xbar_1
⇕ TL00052::UCL_xbar_1
⇕ TL00052::LCL_xbar_1
⇕ TL00052::Rbar
⇕ TL00052::R_1
⇕ TL00052::UCL_rbar_1
⇕ TL00052::LCL_rbar_1

Options

Output file character set: Unicode (UTF-16) ▼

☐ Apply current layout's data formatting to exported data

OK   Cancel