TRACKING THE QUALITY OF A BIOMEDICAL/CLINICAL ENGINEERING UNIT USING STATISTICAL PROCESS CONTROL

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B.S. in Biomedical Engineering,
Faculty of Engineering, Başkent University, 2007

Submitted to the Institute of Biomedical Engineering
in partial fulfillment of the requirements
for the degree of
Master of Science
in
Biomedical Engineering

Boğaziçi University
2009

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DATE OF APPROVAL: 14.09.2009

ACKNOWLEDGMENTS

The undertaking of this extensive work could never be accomplished without the contribution and support of many individuals. I wish to thank my advisor, Assoc. Prof. Dr. Albert Güveniş for giving me the opportunity to work in a very interesting area, and for his support and guidance throughout my study. Without his persistent help this dissertation would not have been possible.

I thank the members of my committee for their time and effort as well as TUBİTAK - BİDEB 2210 for the financial support of my master.

I thank my parents, Nilüfer - Erhan Türegün, for their love and support.

I am grateful to my friend, Metin Yentür, for his advice, supervision, and expertise in C# - which made him a backbone of this research and so to this thesis.

In addition, I would like to thank biomedical engineering and continuous quality improvement departments at V.K.V. Amerikan Hastanesi, Teşvikiye, Istanbul, for access to the maintenance, repair, equipment and stock management data.

Last of all, my special thanks to Dr. Özlem Yıldırım, the manager of continuous quality improvement department at V.K.V. Amerikan Hastanesi, Teşvikiye, Istanbul, for her supervision, advice, and guidance as well as giving me extraordinary experiences through out the time we work together. Her influence during the final chapters of my formal education has shaped the scientist and engineer I have aspired to become.

ABSTRACT

TRACKING THE QUALITY OF A BIOMEDICAL/CLINICAL ENGINEERING UNIT USING STATISTICAL PROCESS CONTROL

Since, healthcare is an ever-changing environment, it is vital for each institution to be prepared to face and consequently conquer technological future advancements in medicine. This can be accomplished by careful selection of appropriate indicators which are essential to measure the performance and quality of processes and their improvements. Statistical process control (SPC) is a key approach to quality improvement. Control charts, central to SPC, are used to visualize and analyze the performance indicators over time.

In this study, SPC principles were incorporated into .NET Framework on MS Windows to design and develop a control system for biomedical engineering departments in hospitals. With the use of the software developed, biomedical/clinical engineering departments' processes were analyzed using real time SPC techniques (X control chart and Cusum control chart), which permitted monitoring, controlling and improving the implementation of different quality and performance indicators through analysis. This expert system enables the user to be notified of any potential problems, just in time to implement various techniques for their improvement.

Keywords: Biomedical Engineering, Quality Indicators, SPC, CUSUM.

ÖZET

İSTATİSTİKSEL SÜREÇ KONTROL İLE BİYOMEDİKAL(KLİNİK) MÜHENDİSLİK BİRİMLERİNİN KALİTE TAKİBİ

Sağlık alanı sürekli değişen bir ortam olduğu için, kurumların tıp alanındaki teknolojik gelişmelerle karşılaşmaya sürekli hazır olmaları ve bu gelişmeleri benimsemeleri gereklidir. Bu, süreçlerin kalitelerinin ve performanslarının ve ilerlemelerinin ölçümü için esas olan ,uygun göstergelerin seçimiyle başarılabilir. İstatiksel Süreç Kontrol (İSK) kalite geliştirmenin anahtar yaklaşımıdır. İSK'nın eası olan kontrol tabloları, performans göstergelerini zaman üzerinde görselleştirmek ve analiz etmek için kullanılır.

Bu çalışmada, İSK prensipleri hastanelerdeki biyomedikal/klinik mühendislik bölümleri için bir kontrol sistemi tasarlanması ve geliştirilmesi için MS Windows üzerindeki .NET çatısı içine dahil edilmiştir. Geliştirilen yazılımla, biyomedikal/klinik mühendislik bölümlerinin süreçleri, farklı kalite ve performans göstergelerinin analiz edilerek izlenme, kontrol edilme ve geliştirilmesine izin veren gerçek zamanlı İSK teknikleri (X kontrol tablosu ve Kümülatif toplam kontrol tablosu) kullanılarak analiz edilmiştir. Bu uzman sistem, kullanıcının potansiyel problemlerden, geliştirilmeleri için farklı tekniklerin uygulanması amacıyla tam zamanında haberdar olmasını sağlar.

Anahtar Sözcükler: Biyomedikal Mühendislik, Kalite Göstergeleri, İSK, Kümülatif Toplam.

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σ	Standard Deviation
k	Number of samples
$\bar{X}$	Overall process average
P	Probability that an item will fail to conform to the specification
$\bar{P}$	Average proportion defective
x_i	Number of defective items
n_i	Number of items inspected
μ	Mean
μ_i	Target for the process mean
C_i	Cumulative sum up to and including the i^{th} sample
C^+	One-sided upper cusum
C^-	One-sided lower cusum
K	Reference value
H	Decision interval
N	Number of consecutive periods that the cusums have been nonzero
δ	Size of the shift in standard deviation units

LIST OF ABBREVIATIONS

MS	Microsoft
MAESTRO	Maintenance, Repair, Equipment and Stock Management software
SPC	Statistical Process Control
WHO	World Health Organization
QI	Quality improvement
KPI	Key Performance Indicators
KSI	Key Success Indicators
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
CE	Clinical Engineering
PEFR	Peak Expiratory Flow Rate
SD	Standard Deviation
UCL	Upper Control Limit
LCL	Lower Control Limit
CL	Center Line
UWL	Upper Warning Line
LWL	Lower Warning Line
WECO	Western Electric Company
ARL	Average Run Length
ART	Average Response Time
PM	Preventive Maintenance
PCA	Patient-Controlled Analgesia
MRI	Magnetic Resonance Imaging
CT	Computerized Tomography
CPM	Continuous Passive Motion
CR	Computerized Radiography
EECP	Enhanced External Counterpulsation
EEG	Electroencephalography
ECG	Electrocardiography

ECHO	Echocardiography
EMG	Electromyography
IABP	Intra Aortic Balloon Pump
TCP/IP	Transmission Control Protocol / Internet Protocol
XML	Extensible Markup Language
SOAP	Simple Object Access Protocol
HTTP	Hypertext Transfer Protocol
VB	Visual Basic
FIR	Fast Initial Response

1. INTRODUCTION

The term "quality" is defined as any factor that enhances the value of a product in the eyes of the customer [1]. This customer-oriented definition of quality has changed the philosophy in service industry, and thus in hospital environments. In order to provide a good service that meets "customer" requirements, it is of utmost importance to have a process operating on target. Hence, quality control has become a key part of every hospital process.

Quality improvement constitutes also an important concept in the biomedical/clinical engineering departments within hospital environments. It is thus essential to provide these departments with successful ways of attaining high standards in controlling and continuously monitoring their diverse processes.

In this study, we started with a simple idea: how can we help to improve our colleagues' performances and quality of our profession in hospital environments? We carried out an extensive literature survey and finally decided to help to improve the data modeling and data monitoring part. There were some previous work performed before us [2], so we started from where they stop.

Izabella A. Gieras, Eric Rosow, Joseph Adam, Chris Roth, and John D. Enderle developed a control system for the implementation of different quality and performance indicators in healthcare. Five indicators were selected in the Biomedical Engineering Department at Hartford Hospital, Hartford, Connecticut: number of medical equipment breakdowns, total number of work orders, average hours and cost per service call and percentage of completed preventive maintenance inspections. They measured these indicators in six departments, namely Anesthesia, Biomedical Engineering, Hemodialysis, Operating Rooms, Radiology and Respiratory Care. They used data from the biomedical engineering medical equipment database, WOSYST (St. Croix System) and stored in MS Excel. With the use of LabVIEW, they modeled appropriate indi-

cators with various statistical tools, such as control and Pareto charts and histograms. With the use of expert system designed in LabVIEW, they thought that the user could be notified of any potential problems, just in time to implement various techniques for their improvement [2].

The primary objective of our study is also to design and develop a control system especially for biomedical/clinical engineering departments in hospital environments to monitor, control and improve implementation of different quality and performance indicators.

Eight indicators were selected in the Biomedical/clinical engineering Department at V.K.V. Amerikan Hastanesi, Istanbul: Average Response Time, Average Repair Time, Average In-house Repair Time, Total Cost per Repair, Fraction of failures, Total Maintenance Rate, Uncompleted Calibration Rate and Uncompleted Preventive Maintenance Rate. Some were analyzed weekly and monthly, and some were analyzed per device, per department and per employee. Since we use the Maintenance, Repair, Equipment and Stock Management software (MAESTRO) of the hospital, it is not our choice to determine the data which the software should collect. But it is our choice to select the departments and the devices.

Data, taken from the MAESTRO software, were imported as reports in MS Excel. With the purpose of monitoring data quality, which is outside the scope of our aim here, and making the first interpretations, we used Statistical Process Control (SPC) techniques to model the data in MS Excel before starting to write codes of our software program. SPC is a method of monitoring, controlling and, ideally, improving a process through statistical analysis. It includes measuring processes, eliminating variances in processes to make it consistent, monitoring processes, and improving processes to their best target value [3].

Appropriate indicators were modeled with some SPC tools with the use of .NET Framework. With .NET Framework, the user can be notified of any potential problems, just in time to implement various techniques for their improvement. Thus, the designed

system established an extensive statistical process control framework, achieving all the major goals as outlined above. This ideally constituted control system can be used effectively by the biomedical/clinical engineering departments as well as other departments to continuously improve quality in healthcare and even in other disciplines.

How we differ from the previous work is, we used a different programming language in a different framework and we use different SPC techniques. In the previous work, they used software package LabView to track quality and decision support. In our study, we used C# to write our software in .NET Framework. Since this is a MS Windows framework, it is easier to work with than with LabView, which provides more flexibility and higher performance. The second main difference is that they use various statistical tools, such as Shewhart control and pareto charts and histograms. We use Shewhart control charts, too but we also implement Cusum charts for better sensitivity.

All these differences and aspects of our work will be discussed in the oncoming chapters. The first part will be an expanded version of the introduction, basically giving some background information about the quality definitions, quality improvement in healthcare, performance measurement and the relationship between quality and biomedical/clinical engineering.

The second part is the "methods" part and is mostly about statistical process control. Theory of statistical process control, used statistical process control tools and examples of how to use them will be discussed. How we chose the key performance indicators and how they are calculated are also other important features of this part.

The third part is about the designed software system. Selection of the programming language, how to transfer the data, the user interface and how to use the software are the main topics. Finally, the results will be clarified, the advantages and disadvantages will be discussed and the future work will be announced.

2. QUALITY AND QUALITY IMPROVEMENT IN HEALTHCARE

Defining quality in health care can be complex and controversial. There are a variety of arguments on its definition because of the different views of people with a stake in good health care. Different stakeholders for healthcare can be listed as:

- Providers
- Payers
- Employers
- Patients

Providers tend to view quality in a technical sense - accuracy of diagnosis, appropriateness of therapy, resulting health outcome while payers focus on cost-effectiveness. Employers want both to keep their costs down, and to get their employees back to work quickly and the patients want compassion as well as skill with clear communication [4].

The World Health Organization (WHO) suggests:

"Quality is a process of meeting the needs and expectations of patients and health service staff."

To sum up, three ingredients go into quality. The first ingredient is patient satisfaction - which has nothing to do with the technical effectiveness of the care. It has to do with the humaneness and responsiveness with which the patient is treated. The second ingredient is precisely the technical effectiveness of care and the third ingredient is improvement from year to year in that technical effectiveness as well as in efficiency [5].

In the view of these information, it can be concluded that improved quality delivers better patient care at lower costs with potentially higher reimbursements.

Quality improvement (QI) represents a promising strategy for improving hospital quality of care. It is a formal approach to the analysis of performance and systematic efforts to improve it. QI emphasizes continuous examination and improvement of work processes by teams of organizational members trained in basic statistical techniques and problem solving tools and empowered to make decisions based on their analysis of the data. It focuses analyzing the root causes of variability, taking appropriate steps to make work processes predictable, and then continuously improving process performance [6].

So, like Mary Ann Bailey, The Hastings Center, explains:

"Health Care Quality Improvement is a broad range of activities of varying degrees of complexity and methodological and statistical rigor through which health care providers develop, implement and assess small-scale interventions and identify those that work well and implement them more broadly in order to improve clinical practice."

2.1 Measuring Quality Improvement

Improvement of health care requires making changes in processes of care and service delivery. Process performance is measured to determine if these changes are having the desired beneficial effects [7].

Debates in health care quality forums have shifted in recent decades from whether quality can be measured to how best to measure quality in health care. The ultimate goal of health systems is the optimization of the health of treated individuals and populations, and the "gold standard" for quality measurement will thus always be health outcome measures. When measuring the performance of a system it is important

to consider the complete process involved in turning inputs into outputs and evaluating the outcomes against a defined set of objectives. The challenges in developing and implementing measurement sets appropriate to the needs of the various participants in health care (purchasers, providers and consumers) are considerable and the use of health status measures within a health outcomes quality monitoring framework does have difficulties [8]. The difficulty in measuring healthcare outputs and attributing them to system performance is that an outcome may be the result of many factors [9]. Rather then looking at a final outcome, most experts advocate evaluation of the process of delivering care. The assumption is that if appropriate care is delivered in a timely fashion, patient outcome will be improved [10].

2.1.1 Performance Indicators

Key Performance Indicators, also known as KPI or Key Success Indicators (KSI), help an organization define and measure progress toward organizational goals [11].

KPI can be thought as surrogate markers that reflect overall quality [12] and are vital to measure the performance and quality of processes and their contribution to strategies and opportunities [9].

Each health care organization must identify and prioritize which processes and outcomes are important for monitoring performance, based on its mission and the scope of care and services it provides.

Monitoring performance depends on the identification of performance indicators for each service, process, or outcome determined important to track. Performance indicator is a "quantitative tool (for example, a rate, ratio, index, percentage) that provides an indication of an organization's performance in relation to a specified process or outcome" (JCAHO 2005).

KPI enable objective assessment of department and trust position, meaningful discussion of service performance with customers and a means of identifying risks [13] and monitoring selected indicators can help an organization determine process stability or can identify improvement opportunities.

Specific criteria are used to define the organization's performance indicators. Components of a good performance indicator include a documented numerator statement, a denominator statement, and a description of the population to which the measure is applicable. In addition, the measurement period; baseline goal; data collection method; and frequency of data collection, analysis, and reporting, must be identified [14].

In this study, to visualize the experimental part of the developed program for biomedical/clinical engineering departments, the required performance data is taken from the maintenance, repair, equipment and stock management software package MAESTRO, which is currently used for monitoring and collecting data for technical departments in V.K.V. Amerikan Hastanesi, Istanbul.

KPI are decided through a tense literature search and on-site surveys with engineers, technicians and staff working in biomedical/clinical engineering department. How the KPI are chosen and calculated will be discussed in detail in further chapters.

2.2 Quality and Biomedical/Clinical Engineering

Performance measurement have become an integral component of all health care delivery settings and the biomedical/clinical engineering (CE) department can not be overlooked. Throughout its history, clinical engineering has focused on medical devices as they are used in healthcare delivery settings: dealing with acquisition of appropriate equipment; inspection, maintenance, and repair; regulatory compliance; and related technical issues. Over time, clinical engineering has assumed a leading role in management of medical equipment during its entire life span of use [15].

If a service providing sector, like CE departments, decides to differentiate itself in the market place on the basis of quality of service, then, amongst other things, it should be monitoring and controlling the desired level of quality [16]. In order to assess ongoing performance, identify new quality improvement opportunities, and monitor the effect of improvement action plans, CE departments need to gather objective and quantifiable data. This must be a continuous process implemented by each department and actively monitored on regular basis. For this reason, indicators were developed to measure overall performance of the department [2]. The optimum goal of benchmarking performance indicators in the CE department is to continuously strive to improve the quality of the CE department's services upstream, which will consequently lead to a better financial performance downstream [17].

2.3 Statistical Process Control (SPC) in Health Care

One of the tenets of QI is that to improve healthcare performance we must change our way of working [18]. Improvement of health care requires making changes in processes of care and service delivery. But not all these change results in improvement [19]. Although process performance is measured to determine if these changes are having the desired beneficial effects, this analysis is complicated by the existence of natural variation - that is, repeated measurements naturally yield different values and, even if nothing was done, a subsequent measurement might seem to indicate a better or worse performance.

Traditional statistical analysis methods account for natural variation but require aggregation of measurements over time, which can delay decision making. Statistical process control (SPC) is a branch of statistics that combines rigorous time series analysis methods with graphical presentation of data, often yielding insights into the data more quickly and in a way more understandable to lay decision makers [7].

For example, the Joint Commission on Accreditation of Healthcare Organizations recently stated their position on the use of SPC as follows [20]:

"An understanding of statistical quality control, including SPC, and variation is essential for an effective assessment process. Statistical tools such as run charts, control charts, and histograms are especially helpful in comparing performance with historical patterns and assessing variation and stability."

Statistical process control (SPC) is a philosophy, a strategy, and a set of methods for ongoing improvement of systems, processes, and outcomes. The SPC approach is based on learning through data and incorporates the concepts of an analytic study, process thinking, prevention, stratification, stability, capability, and prediction. SPC incorporates measurement, data collection methods, and planned experimentation [21]. Control charts, which will be discussed later in the oncoming chapter, are used to visualize and analyze the performance of a process over time, and sometimes in real time.

All these information indicates that SPC can indeed be a powerful and versatile tool for managing changes in healthcare through QI. Besides helping diverse stakeholders manage and improve healthcare processes, SPC can also help clinicians and patients understand and improve patients' health when applied directly to health indicators such as peak expiratory flow rate (PEFR) in asthma or blood sugar concentrations in diabetes [22].

3. STATISTICAL PROCESS CONTROL (SPC)

3.1 Theory of Statistical Process Control

The basic theory of statistical process control was developed in the late 1920s by Dr Walter Shewhart, [23] a statistician at the AT&T Bell Laboratories in the USA, and was popularized worldwide by Dr W Edwards Deming [24]. Both observed that repeated measurements from a process will exhibit variation for example, re-measurement of a patient's blood pressure, a department's waiting times, or appointment access satisfaction.

If a process is stable, its variation will be predictable and can be described by one of several statistical distributions.

One such model of random variation is the normal (or Gaussian) bell shaped distribution. While repeated measurements from many processes follow normal distributions, there are many other types of distributions that describe the variation in other healthcare measurements such as Poisson, binomial, or geometric distributions.

SPC theory uses the phrase "special cause variation" to refer to unnatural variation due to events, changes, or circumstances that have not previously been typical or inherent in the regular process.

Special cause variation can be the result of either a deliberate intervention or an external event over which we have little control. Special causes of variation can also be transient or can become a part of the permanent common cause system. Because processes that exhibit special cause variation are unstable and unpredictable, they should be improved by first eliminating the special causes in order to bring the process "into control".

Conversely, the phrase ”common cause variation” to refer to the natural variation inherent in a process on a regular basis. This is the variation that is expected to occur according to the underlying statistical distribution if its parameters remain constant over time.

Processes that exhibit only common cause variation are said to be in control. If a process remains in control, future measurements will continue to follow the same probability distribution as previously-that is, if a stable process produces data that follow a normal distribution and it is not further disturbed by special causes, we can expect about 95% of future measurements to fall within two standard deviations (SD) around the mean. We can make similar statements about prediction ranges associated with any other statistical distribution. In general, regardless of the underlying distribution, almost all data will fall within 3σ (SD) of the mean if the underlying distribution is stable-that is, if the process is in statistical control [7].

3.2 Statistical Process Control Tools

In SPC numbers and information will form the basis for decisions and actions, and a thorough data recording system is essential. In addition to the basic elements of a management system, which will provide a framework for recording data, there exists a set of "tools" which may be applied to interpret fully and derive maximum use of the data [25].

Statistical tools are therefore needed to help distinguish whether patterns in a set of measurements exhibit common or special cause variation. While statistical process control charts and hypothesis tests are both designed to achieve this goal, an important difference is that SPC provides a graphical, simpler, and often faster way to answer this question [7].

The simple methods listed below will offer any organization a means of collecting, presenting and analyzing most of its data and can help both researchers and

practitioners of quality improvement to determine whether changes in processes are making a real difference in outcomes:

- Process flowcharting
- Check sheets / tally charts
- Histograms
- Graphs
- Pareto analysis
- Cause and effect analysis and brainstorming
- Scatter diagrams
- Control charts [27]

In the following sections and chapters only "the control chart" will be explained and discussed because only several types of these "control charts" were used. Other statistical process control tools (listed above) all lie outside the scope of this study.

3.3 The Control Chart

Statistical process control charts are chronological graphs of process data that are used to help understand, control, and improve processes - including biological processes such as blood pressure homoeostasis or organizational processes such as patient care in a hospital [22] - and that, although based in statistical theory, are easy for practitioners to use and interpret. The control chart therefore defines what the process is capable of producing given its current design and operation [7].

Control charts have several important, somewhat sequential, roles in quality improvement work. These roles are discussed in greater detail [26] and include:

- Understanding current and past process performance and its degree of consistency and predictability
- Establishing a "state of statistical control" by identifying and removing causes of unnatural (or "special cause") variation so as to achieve a consistent and predictable level of process quality over time
- Improving a process by identifying and removing causes of natural (or "common cause") variation and by testing whether interventions result in an improvement
- Monitoring for process deterioration and "holding the gains" by identifying special causes of unnatural variation when they arise in the future

While there are several different types of control charts, the general format and interpretation of the most common and simplest type, called Shewhart control charts, originally were developed by Shewhart in 1924, one for each of several types of data that are commonly encountered in practice. Each of these types of data can be described by a statistical distribution that is used to determine the expected value, theoretical standard deviation, and natural variation of the data (i.e., the center line and control limits) [27].

A control chart consists of two parts: a series of measurements plotted in time order and the control chart ”template” which consists of three horizontal lines called the center line (typically, the mean), the upper control limit (UCL), and the lower control limit (LCL). The values of the UCL and LCL are usually calculated from the inherent variation in the data rather than set arbitrarily by the individual making the chart.

The control chart is a very useful process monitoring technique; when unusual sources of variability are present, sample averages will plot outside the control limits. This is a signal that some investigation of the process should be made and corrective action to remove the unusual sources of variability taken. Systematic use of a control chart is an excellent way to reduce variability.

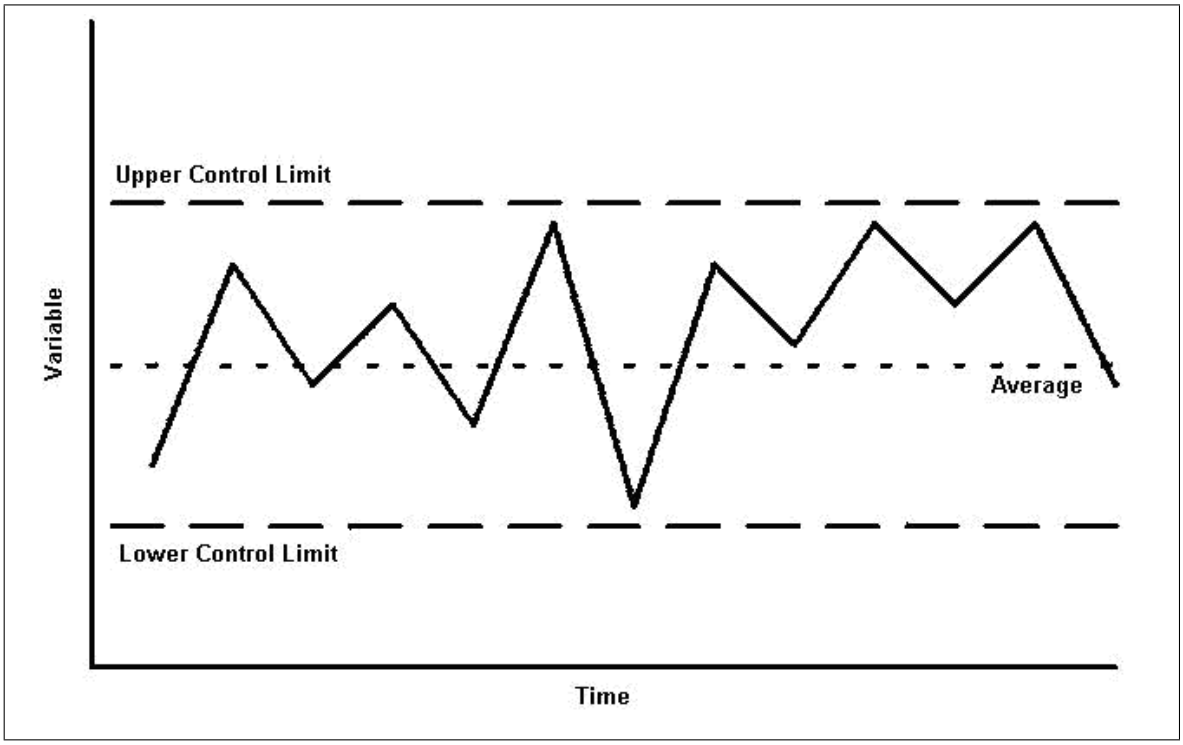


Figure 3.1 The Control Chart

To interpret a control chart, data that fall outside the control limits or display abnormal patterns are indications of special cause variation - that is, it is highly likely that something inherently different in the process led to these data compared with the other data. As long as all values on the graph fall randomly between the upper and lower control limits, however, we assume that we are simply observing common cause variation.

Where to draw the UCL and LCL is important in control chart construction. Shewhart and other SPC experts recommend control limits set at $\pm 3\sigma$ from the mean for detecting meaningful changes in process performance while achieving a rational balance between two types of risks. If the limits are set too narrow there is a high risk of a "type I error" - mistakenly inferring special cause variation exists when, in fact, a predictable extreme value is being observed which is expected periodically from common cause variation. This situation is analogous to a false positive indication on a laboratory test. On the other hand, if the limits are set too wide there is a high risk

of a ”type II error”analogous to a false negative laboratory test.

Regardless of the distribution of the quality characteristic, it is standard practice in the United States to determine the control limits as a multiple of the standard deviation of the static plotted on the chart. The multiple usually chosen is three; hence, three-sigma limits are customarily employed on control charts, regardless of the type of chart employed [28].

In addition to points outside the control limits, we can also look more rigorously at whether data appear randomly distributed between the limits. Statisticians have developed additional tests for this purpose; for example, a common set of tests for special cause variation is:

- One point outside the upper or lower control limits;
- Two out of three successive points more than 2SD from the mean on the same side of the center line;
- Four out of five successive points more than 1SD from the mean on the same side of the center line;
- Eight successive points on the same side of the center line;
- Six successive points increasing or decreasing (a trend); or
- Obvious cyclic behavior.

In return for a minor increase in false positives, these additional tests greatly increase the power of control charts to detect process improvements and deteriorations. The statistical ”trick” here is that we are accumulating information and looking for special cause patterns to form while waiting for the total sample size to increase. This process of accumulating information before declaring statistical significance is powerful, both statistically and psychologically [7].

3.3.1 Individuals Control Chart

One of the most common difficulties that practitioners have in using SPC is determining which type of control chart they should construct.

For example, the three most common types of control charts should be used in the following situations:

- Either an *np* or a *p* control chart should be used when analyzing discrete data that are distributed according to a binomial distribution;
- Either a *c* or *u* control chart should be used when analyzing count data that are distributed according to a Poisson distribution;
- Both an *X-bar* and an *S* chart should be used together for continuous data that are distributed according to a normal distribution [27].

Since, some of our samples were distributed normally and some of them were distributed according to binomial distribution, we chose to use both *X* individuals control charts and *p* control charts according to the type of the data.

The individuals control chart is a type of control chart that can be used with variables data. It examines variation in individual sample results over time. Since we have only individual samples, we only study on individuals control charts.

Individuals control charts should be used when there is only one data point to represent a situation at a given time. The individuals control chart allows the user to plot a point on the chart for each sample taken. This permits you to determine if the process is in statistical control or not for each sample taken.

The individuals control chart is a method of looking at variation. One source of variation is the variation in the individual sample results. This represents "long-term"

variation in the process. The second source of variation is the variation in the ranges between successive samples. This represents "short-term" variation [29].

3.3.2 The Standard X Control Chart

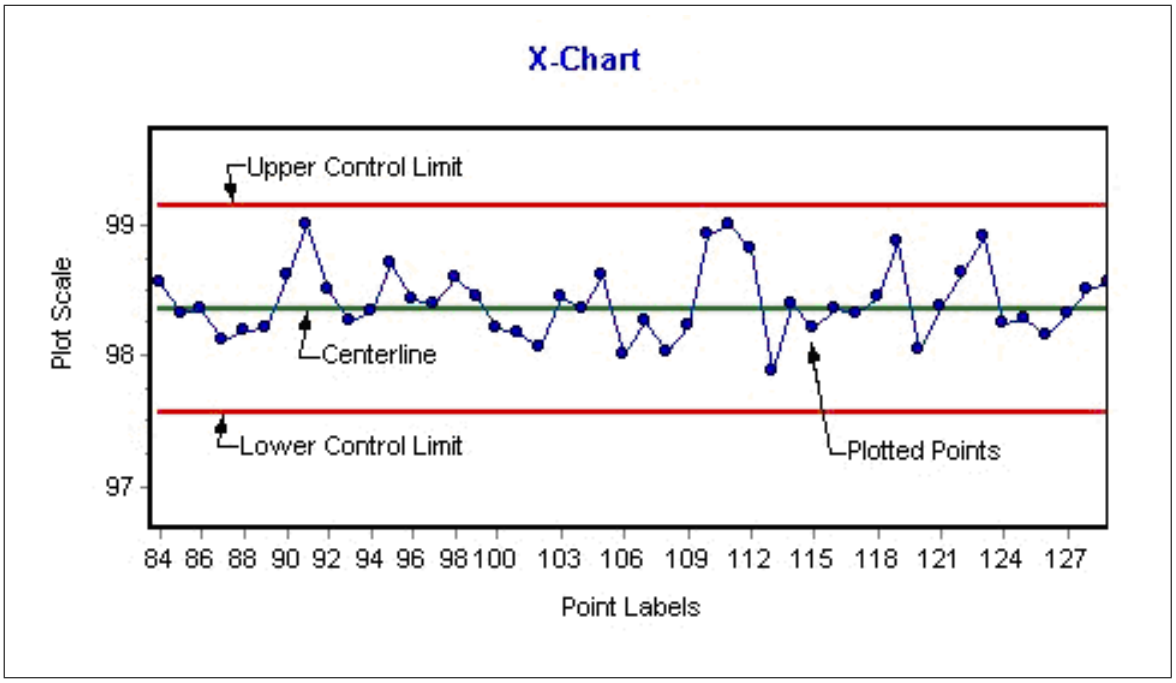


Figure 3.2 The X Control Chart

The figure in this section is an example of an X chart for individual results. The overall process average has been calculated and plotted as a solid line in green. The upper and lower control limits have also been calculated and plotted as solid red lines.

Steps in Constructing:

1. Gathering the data

   - Select the frequency that the data will be collected. Data should be collected in the order in which they are generated.
   - Select the number of data points (k) to be collected before control limits are calculated.

- Record the individual sample results.

2. Plot the data.

   - Select the scales for the x and y axes for the X chart.
   - Plot the individual sample results on the X chart and connect consecutive points with a straight line.

3. Calculate the overall process averages and the control limits.

   - Calculate the overall process average $\bar{X}$

$$\bar{X} = \sum X/(k) \tag{3.1}$$

   - Plot $\bar{X}$ on the X chart as a solid line and label as "Center Line".
   - Calculate the standard deviation for the individuals measurements.
   - Calculate the control limits for the X chart. The upper control limit is given by UCL_x. The lower control limit is given by LCL_x.

$$UCL_x = \bar{X} + 3\sigma \tag{3.2}$$

$$LCL_x = \bar{X} - 3\sigma \tag{3.3}$$

     (If LCL is less than or equal to 0 then, LCL = 0)[30]

   - Plot the control limits on the X chart and label them [29].

4. Interpret the chart for statistical control.

Western Electric put out a handbook in 1956 to determine the rules for interpreting the process patterns. These rules are based on the probability for the points to plot at specified areas of the control charts.

A process is said to be "out-of-control" if the following occur:

Table 3.1
The Weco (Western Electric Company) Rules

Any Point Above +3 Sigma
———————————— +3 σ LIMIT
2 Out of the Last 3 Points Above +2 Sigma
———————————— +2 σ LIMIT
4 Out of the Last 5 Points Above +1 Sigma
———————————— +1 σ LIMIT
8 Consecutive Points on This Side of Control Line
========== CENTER LINE
8 Consecutive Points on This Side of Control Line
———————————— -1 σ LIMIT
4 Out of the Last 5 Points Below - 1 Sigma
————————————- -2 σ LIMIT
2 Out of the Last 3 Points Below -2 Sigma
———————————— -3 σ LIMIT
Any Point Below -3 Sigma

Trend Rules: 6 in a row trending up or down. 14 in a row alternating up and down [31]

The WECO (Western Electric Company) rules are based on probability. For a normal distribution, the probability of encountering a point outside $\pm 3\sigma$ is 0.3%. This is a rare event. Therefore, if we observe a point outside the control limits, we conclude the process has shifted and is unstable. Similarly, we can identify other events that are equally rare and use them as flags for instability. The probability of observing two points out of three in a row between 2σ and 3σ and the probability of observing four points out of five in a row between 1σ and 2σ are also about 0.3% [32].

Since The WECO rules are very good guidelines for interpreting the charts, we choose to use this set of rules. But they need to be used with caution because they add sensitivity to the trends of the mean. While the WECO rules increase a Shewhart chart's sensitivity to trends or drifts in the mean, there is a severe downside

to adding the WECO rules to an ordinary Shewhart control chart that the user should understand. When following the standard Shewhart "out-of-control" rule (i.e., signal if and only if you see a point beyond the plus or minus 3 sigma control limits) you will have "false alarms" every 371 points on the average. Adding the WECO rules increases the frequency of false alarms to about once in every 91.75 points, on the average [33]. The user has to decide whether this price is worth paying (some users add the WECO rules, but take them "less seriously" in terms of the effort put into troubleshooting activities when out-of-control signals occur).

3.3.2.1 An Individuals X Control Chart Example. Let's assume that our hospital's biomedical/clinical engineering department has just implemented a promise that in-house repair time will never be longer than one week (10080 minutes). We decided to find out if this is really true. Since we can only gather the needed data about once a month, we have infrequent data. We felt that the individual measurements (time for in-house repair) are probably a normal distribution. We decided to use an individuals X control chart to determine if the biomedical/clinical engineering department is keeping its promise. The results for measurement of 13 months are given below in table 3.2.

The first step after collecting the data is to calculate the overall process average. The overall process average is determined by adding up the individual results for each month and dividing by the number of samples (months). In this case, the number of months (k) is 13.

$$\bar{X} = 23476/13 = 1806 \tag{3.4}$$

The second step is to calculate the standard deviation. Standard deviation is calculated by the formula below since the sample is assumed to be normally distributed.

Table 3.2
In-house repair times (in minutes) per month

Months	Minutes
February.08	2145
March.08	1905
April.08	2035
May.08	1964
June.08	2405
July.08	1708
August.08	1675
September.08	2176
October.08	1638
November.08	1420
December.08	1382
January.09	1809
February.09	1214

$$\sigma = \sqrt{\frac{\sum (X - \bar{X})^2}{(k-1)}} = 346 \tag{3.5}$$

The next step is to calculate the control limits. The control limits are:

$$UCL_x = \bar{X} + 3\sigma = 1806 + 3(346) = 2844 \tag{3.6}$$

$$LCL_x = \bar{X} - 3\sigma = 1806 - 3(346) = 768 \tag{3.7}$$

The individuals X control chart for in-house repair time is shown in figure 3.3. The process is in control. Since no points fall outside the control limits, we assumed that we are simply observing common cause variation. This means, that as long as the process stays the same, we can predict, within a range, how long it will take the biomedical/clinical engineering department to finish off the in-house repairs.

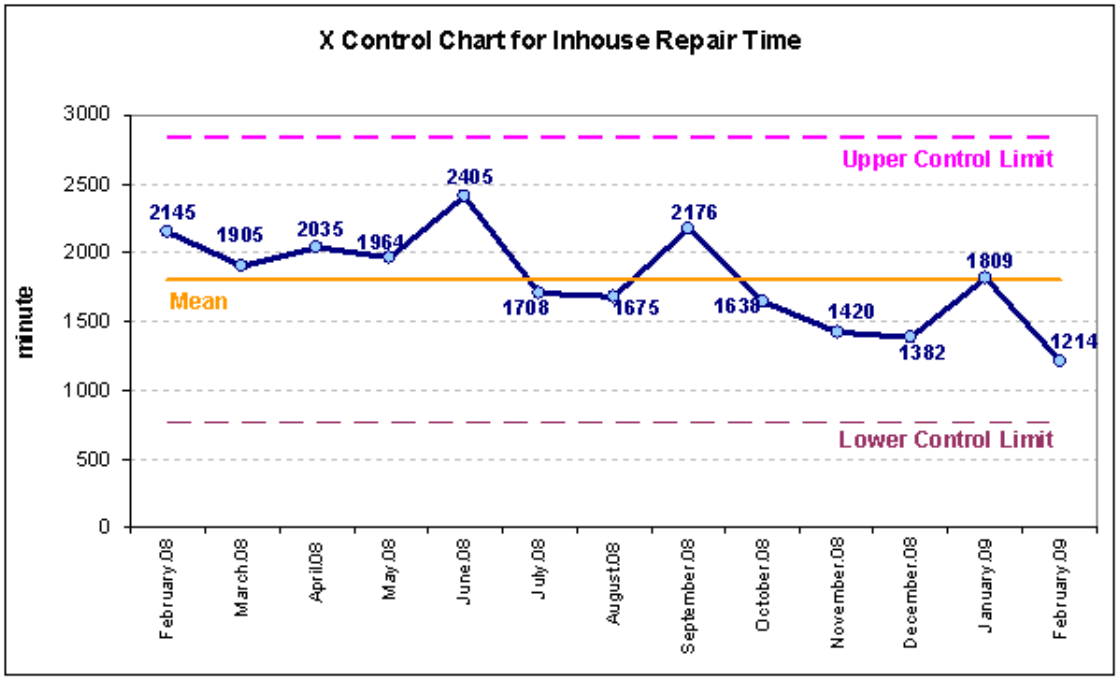


Figure 3.3 The X Control Chart for In-house Repair Times

This means that, when a device comes to the biomedical/clinical engineering department, it will wait in line anywhere from 768 to 2844 minutes. What does this mean about your hospital's commitment that in-house repair time will never be longer than one week (10080 minutes)? It means that the hospital is capable of meeting that guarantee.

3.3.3 The P Control Chart

A p control chart is used to look at variation in yes/no type attributes data. There are only two possible outcomes: either the item is defective or it is not defective. The p control chart is used to determine if the fraction of defective items in a group of items is consistent over time.

A product or service is defective if it fails to conform to specifications or a standard in some respect. For example, consider the case of a patient having a surgery. The patient would probably not like to have a surgical site infection. Suppose we have

determined that the operational definition for not having a surgical site infection is "not to have a surgical site infection". Using this definition, we could monitor the fraction of surgeries which develop a surgical site infection or which do not develop a surgical site infection. If a patient does not have a surgical site infection after a surgery, the item (having a surgery) is not defective. If the patient has a surgical site infection after a surgery, the item is defective.

Since, a p control chart can be used when there is yes/no type of data, this chart involves counts. To use a p control chart, the counts must also satisfy the following two conditions:

1. "n" items are being counted. A count is the number of items in those n items that fail to conform to specification.
2. Suppose p is the probability that an item will fail to conform to the specification. The value of p must be the same for each of the n items in a single sample.

If these two conditions are met, the binomial distribution can be used to estimate the distribution of the counts and the p control chart can be used [29].

Steps in Constructing:

The data required for the design of a p control chart are the sample size and the numbers of defectives need to be observed. The first step in the design of a p control chart is the calculation of the average proportion defective ($\bar{P}$).

$$\bar{P} = \sum_{i=1}^{k} x_i / \sum_{i=1}^{k} n_i \tag{3.8}$$

where k is the number of samples;

$\sum_{i=1}^{k} x_i$ = total number of defective items;

$\sum_{i=1}^{k} n_i$ = total number of items inspected.

The next step is calculating the action and warning lines. If a constant sample size is being inspected, the p control chart limits would remain the same for each sample. When p control charts are being used with samples of varying sizes, the standard deviation and control limits change with n, and unique limits should be calculated for each sample size. However, for practical purposes, an average sample size may be used to calculate action and warning lines. These have been found to be acceptable when the individual sample or lot sizes vary from the average sample size by no more than 25 per cent each way. For sample sizes outside this range, separate control limits must be calculated [27].

The control chart lines may be calculated using a value of σ given by:

$$\sigma = \sqrt{\frac{\bar{P}(1-\bar{P})}{\sqrt{n}}} \tag{3.9}$$

Then,

Action lines $(UCL, LCL) = \bar{P} \pm 3\sigma$

Warning lines $(UWL, LWL) = \bar{P} \pm 2\sigma$

3.3.3.1 A P Control Chart Example. A team in the biomedical/clinical engineering department in a hospital has been working on improving Uncompleted Calibration Rates. The team is trying to complete all the scheduled calibrations through the year. The team developed the following operational definition for the defective state: a calibration is though to be "uncompleted (defective)" if the scheduled order is not closed. The team decided to observe all the medical equipment that is subject to calibration monthly.

Table 3.3
Number and fractions of uncompleted calibrations

	Calibrations planned (n)	Number of uncompleted calibrations (x)	Fraction Uncompleted Calibrations (p)
January	20	1	0,05
February	41	3	0,0732
March	3	0	0
April	387	12	0,031
May	391	23	0,0588
June	14	0	0
July	58	0	0
August	42	4	0,0952
September	66	7	0,1061
October	115	9	0,0783
November	76	2	0,0263
December	13	0	0

These data will be used to construct a p control chart. The p values for each subgroup (month) have been calculated and are shown in the table. For example, for January, there was 1 uncompleted calibration order (x) found in the 20 scheduled calibration orders inspected. Thus, p = x/n = 1/20 = 0,0500 or 5%. The p values for the other months are calculated similarly.

The next step is to calculate the average fraction defective. To determine the average, we add up all the x values and divide by the sum of all the n values. The sum of the x values is 61; the sum of the n values is 1226. The average is then calculated as shown in the top equation in this section.

$$\bar{P} = \frac{\sum x}{\sum n} = \frac{61}{1226} = 0,0498 = 4,98\% \tag{3.10}$$

The next step is to determine the average subgroup size. Average subgroup calculation is shown in the equation where k is the number of subgroups.

$$\bar{n} = \frac{\sum n}{k} = \frac{1226}{12} = 102,1669 \tag{3.11}$$

The next step is to calculate the control limits. The control limits calculations are shown below.

$$UCL_p = \bar{P} + 3\sqrt{\frac{\bar{P}(1-\bar{P})}{\bar{n}}} = 0,0498 + 3\sqrt{\frac{0,0498(1-0,0498)}{102,1669}} = 0,1144 = 11,44\% \tag{3.12}$$

$$LCL_p = \bar{P} - 3\sqrt{\frac{\bar{P}(1-\bar{P})}{\bar{n}}} = 0,0498 - 3\sqrt{\frac{0,0498(1-0,0498)}{102,1669}} = -0,0148 \cong 0 = 0\% \tag{3.13}$$

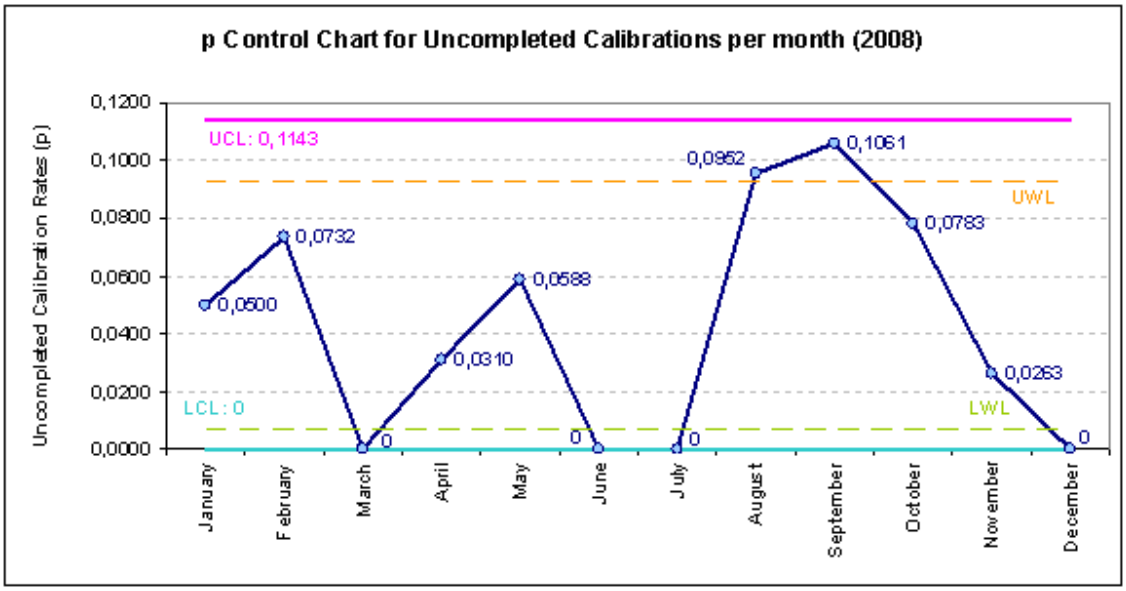


Figure 3.4 P control chart for uncompleted calibrations per month

The p control chart for uncompleted calibrations is shown in this example. Note that there are no points outside the upper and lower control limits. Before we conclude that the process is in control at this level, we could examine the patterns for runs and other non random patterns. There is no strong evidence of anything other than a random pattern of variation about the center line. We conclude that the process is in control at the level $\bar{p} = 0,0498$.

3.3.4 The Cumulative Sum Control Chart

In previous sections, we have considered Shewhart control charts for variables and attributes. These charts are extremely useful in phase I implementation of SPC, where the process is likely to be out-of-control and experiencing assignable causes that result in large shifts in the monitored parameters. Shewhart charts are also very useful in the diagnostic aspects of bringing an unruly process into statistical control, because the patterns on these charts often provide guidance regarding the nature of the assignable cause [28].

The basic rules for the operation of these charts predominantly concern the interpretation of each sample plot. Investigative and possibly corrective action is taken if an individual sample point falls outside the action lines, or if two consecutive plots appear in the warning zone - between warning and action lines. Essentially, process control by Shewhart charts considers each point as it is plotted [27]. This feature makes the Shewhart control chart relatively insensitive to small process shifts, say, on the order of about 1.5σ or less. This potentially makes Shewhart control charts less useful in phase II monitoring problems, where the process tends to operate in control, reliable estimates of the process parameters (such as the mean and standard deviation) are available, and assignable causes do not typically result in large process upsets or disturbances.

A very effective alternative to the Shewhart control chart may be used when small process shifts are of the interest: the cumulative sum (or cusum) control chart.

Cusum control charts are excellent alternatives to the Shewhart control chart of phase II process monitoring situations. This type of chart was first described by Page in 1954 [34] and is based on sequential monitoring of a cumulative performance measure over time. With several developments and adaptations, it has emerged as a suitable method for monitoring healthcare outcomes [35]-[39].

Basic Principles:

Table 3.4
Data for the cusum example

	(a)	**(b)**	**(c)**	**(d)**	**(e)**
	Medical Devices Inspected (n)	Number of failures (x)	Fraction of Failures	$x_i - 0,0586$	$C_i = (x_i - 0,0586) + C_{i-1}$
January	3486	154	0,0442	-0,014	-0,014
February	3486	183	0,0525	-0,006	-0,021
March	3486	167	0,0479	-0,011	-0,031
April	3486	205	0,0588	0	-0,031
May	3486	201	0,0577	-0,001	-0,032
June	3486	232	0,0666	0,008	-0,024
July	3486	210	0,0602	0,002	-0,022
August	3486	221	0,0634	0,005	-0,018
September	3486	218	0,0625	0,004	-0,014
October	3486	229	0,0657	0,007	-0,007
November	3486	243	0,0697	0,011	0,004
December	3486	189	0,0542	-0,004	0

A team in the biomedical/clinical engineering department in a hospital has been working on improving the availability of the medical equipment. The team is trying to reduce breakdown times of the medical devices by decreasing the fraction of number of failures. The team developed the following operational definition for a defective device: a device is defective if the user can not use it properly. The team decided to observe all the medical equipment in the hospital (3486) monthly.

Consider the data in table 3.4, column (c). The 12 observations were drawn with mean $\mu = 0,0586$ and standard deviation $\sigma = 0,0077$. These observations have been plotted on a Shewart control chart in Fig.5. The center line and three-sigma control limits on this chart are at

UCL = 0,0818

Center Line = 0,0586

LCL = 0,0354

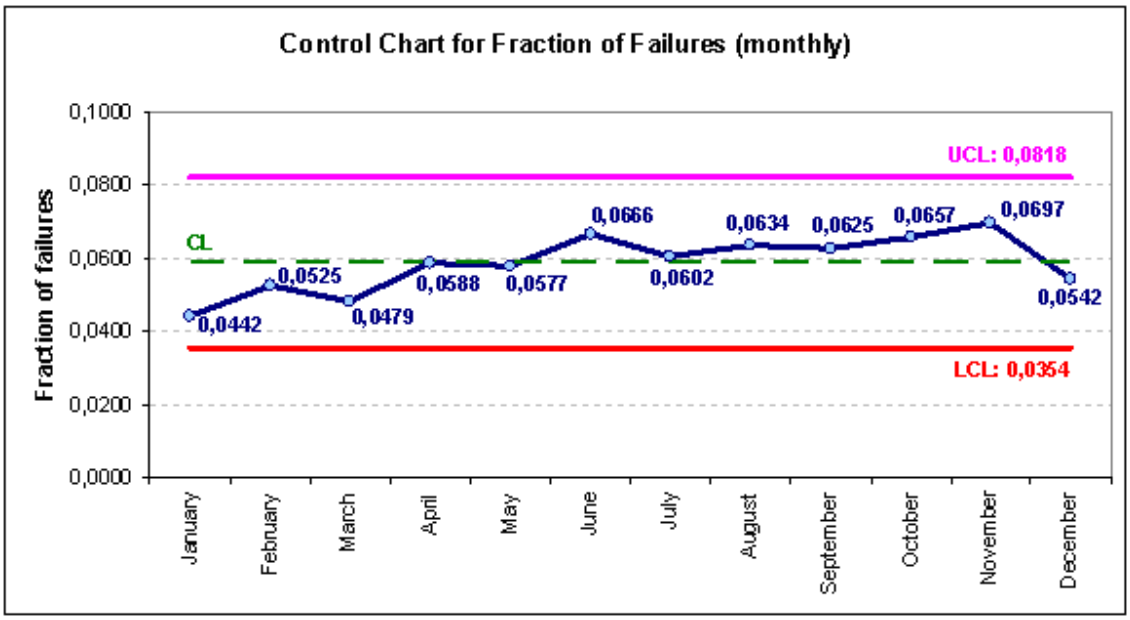


Figure 3.5 P control chart for uncompleted calibrations per month

Note that all 12 observations plot in control.

The 12 observations in column (c) of table 3.4 were divided into two subgroups. The first 6 observation were drawn with mean $\mu = 0,0546$ and standard deviation $\sigma = 0,0081$. The last 6 observation were drawn with mean $\mu = 0,0626$ and standard deviation $\sigma = 0,0052$. Consequently, we can think of these last 6 observations as having been drawn from the process when it is out-of-control - that is, after the process has experienced a shift in the mean of $0,9877\sigma$ (σ is calculated as $\sim 0,0081$).

None of these last 6 points plots outside the control limits, so we have no strong evidence that the process is out-of-control. Note that there is an indication of a shift in process level for the last 6 points, because all but one of the points plot below the center line. However, if we rely on the traditional signal of an out-of-control process, one or more points beyond the three-sigma control limit, then the Shewhart control chart has failed to detect the shift.

The reason for this failure is the relatively small magnitude of the shift. The Shewhart control chart for averages is very effective if the magnitude of the shift is 1,5σ to 2σ or larger. For smaller shifts, the cumulative sum (or cusum) control chart is a good alternative.

The cusum chart directly incorporates all the information in the sequence of sample values by plotting the cumulative sums of the deviations of the sample values from a target value. For example, suppose that samples of $n \geq 1$ are collected, and $\bar{x}_j$ is the average of the j^{th} sample. Then if μ_0 is the target for the process mean, the cumulative sum control chart is formed by plotting the quantity against the sample number i.

$$C_i = \sum_{j=1}^{i} (\bar{x}_j - \mu_0) \tag{3.14}$$

C_i is called the cumulative sum up to and including the i^{th} sample. Because they combine information from several samples, cumulative sum charts are more effective than Shewhart charts for detecting small process shifts. Furthermore, they are particularly effective with samples of size n=1. This makes the cumulative sum control chart a good candidate for use in process industries and that is the reason we choose to use the cusum charts. It is possible to devise cumulative sum procedures for other variables, such as Poisson and binomial variables for modeling disconformities and fraction nonconforming.

We note that if the process remains in control at the target value μ_0 the cumulative sum defined in equation above is a random walk with mean zero. However, if the mean shifts upward to some value $\mu_1 > \mu_0$, say, then an upward or positive drift will develop in the cumulative sum C_i. Conversely, if the mean shifts downward to some $\mu_1 < \mu_0$, then a downward or negative drift in C_i will develop.

Therefore, if a significant trend develops in the plotted points either upward or downward, we should consider this as evidence that the process mean has shifted, and a search for some assignable cause should be performed.

This theory can easily be demonstrated by using the data in column (c) of table 3.4 again. To apply the cusum to these observations, we would take $\bar{x} = x_i$ (since our sample size is n = 1) and let the target value $\mu_0 = 0,0586$. Therefore, the cusum becomes

$$C_i = \sum_{j=1}^{i}(x_j - 0,0586) \tag{3.15}$$

$$= (x_i - 0,0586) + \sum_{j=1}^{i-1}(x_j - 0,0586) \tag{3.16}$$

$$= (x_i - 0,0586) + C_{i-1} \tag{3.17}$$

Column (d) of table 3.4 contains the differences $x_i - 0,0586$, and the cumulative sums are computed in column (e). The starting value for the cusum, C_0, is taken to be zero. Figure 3.6 plots the cusum from column (e) of the table 3.4.

Note that for the first 6 observations where $\mu = 0,0546$, the cusum tends to drift slowly, by going downward a little at first and then upward. However, in the last 6 observations, where the mean has shifted to $\mu = 0,0626$, a strong upward trend develops.

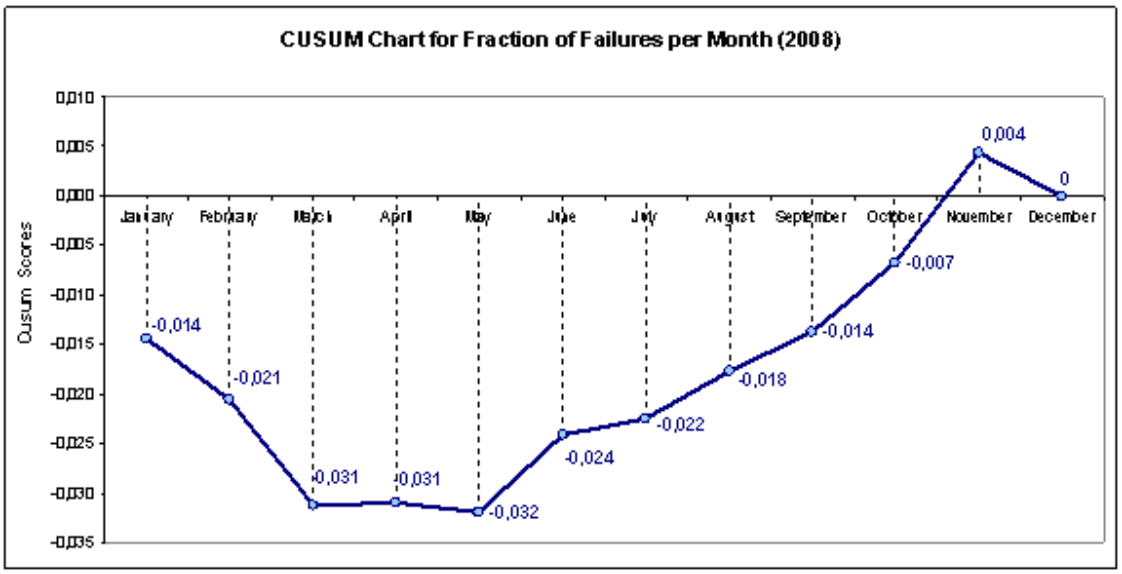


Figure 3.6 The CUSUM Chart for Fraction of Failures per month

The cusum plot in figure 3.6 is not a control chart because it lacks statistical control limits. There are two ways to represent cusums, the tabular (or algorithmic) cusum, and the V-mask form of the cusum. Of the two presentations, the tabular cusum is preferable for several reasons.

1. The V-mask is a two-sided scheme; it is not very useful for one-sided process monitoring problems.

2. The head start feature, which is very useful in practice, cannot be implemented with the V-mask.

3. It is sometimes difficult to determine how far backwards the arms of the V-mask should extend, thereby making interpretation difficult for the practitioner.

4. Ambiguity associated with α and β.

For this reason, we have only implemented the Tabular Cusum not the V - mask procedure.

3.3.4.1 The Tabular Cusum for Monitoring the Process Mean. Cusums may be constructed for both individual observations and for the averages of rational subgroups. Since we worked only with individual observations, cusums for the averages of subgroups will not be discussed here.

Let x_i be the i^{th} observation on the process. When the process is in control, x_i has a normal distribution with mean μ_0 and standard deviation σ. We assume that either σ is known or a reliable estimate is available. These assumptions are very consistent with phase II applications of SPC, the situation in which the cusum is most useful.

The tabular cusum works by accumulating deviations from μ_0 that are above the target with one statistic C^+ and accumulating deviations from μ_0 that are below target with another statistic C^-. The statistics C^+ and C^- are called one-sided upper and lower cusums, respectively. They are computed as follows:

$$C_i^+ = max[0, x_i - (\mu_0 + K) + C_{i-1}^+] \tag{3.18}$$

$$C_i^- = max[0, (\mu_0 - K) - x_i + C_{i-1}^-] \tag{3.19}$$

where the starting values are $C_0^+ = C_0^- = 0$.

In equation (3.18) and (3.19), K is usually called the reference value (or the allowance, or the slack value), and it is often chosen about halfway between the target μ_0 and the out-of-control value of the mean μ_1 that we are interested in detecting quickly.

Thus, if the shift is expressed in standard deviation units as $\mu_1 = \mu_0 + \delta\sigma$ (or $\delta = |\mu_1 - \mu_0|/\sigma$),then K is one-half the magnitude of the shift or

$$K = \frac{\delta}{2}\sigma = \frac{|\mu_1 - \mu_0|}{2} \tag{3.20}$$

Note that C_i^+ and C_i^- accumulate deviations from the target value μ_0 that are greater than K, with both quantities reset to zero on becoming negative. If either C_i^+ or C_i^- exceed the decision interval H, the process is considered to be out-of-control [28].

3.3.4.2 a) A Tabular Cusum Example. We will demonstrate the calculations for the tabular cusum by using the data from Table 3.4. Since dividing 12 observations into two groups of 6 observations and calculating the means separately is performed just to clearly see and to prove the shift in the mean, we will not be using these values in this example. Recall that the target value is $\mu_0 = 0,0586$, the subgroup size is n = 1, the whole process standard deviation is $\sigma = 0,00773$, and suppose that the magnitude of the shift we are interested in detecting is $1.0\sigma = 1.0(0,00773) = 0,00773$. Therefore, the out-of-control value of the process mean is $\mu_i = 0,0586 + 0,00773 = 0,0663$.I will use a tabular cusum with $K = \frac{0,00773}{2}$ (because the shift size is 1.0σ and $\sigma = 0,00773$) 00773) and H = 5 (because the recommended value of the decision interval is $H = 5\sigma = 5(0,00773) = 0,0387$).

Table 3.5 presents the tabular cusum scheme. To illustrate the calculations, consider period 1. The equations for C_i^+ and C_i^- are

$$C_i^+ = max[0, x_1 - 0,0625 + C_0^+] \tag{3.21}$$

and

$$C_i^- = max[0, (0,0547 - x_1) + C_0^-] \tag{3.22}$$

since $K = 0,00387$ and $\mu_0 = 0,0586$. Now $x_1 = 0,04418$, so since $C_0^+ = C_0^- = 0$,

$$C_1^+ = max[0, (0,04418 - 0,0625 + 0)] = 0 \tag{3.23}$$

and

$$C_1^- = max[0, (0,0547 - 0,04418 + 0)] = 0,0105 \tag{3.24}$$

For period 2, we would use

$$C_2^+ = max[0, x_2 - 0,0625 + C_1^+] \tag{3.25}$$

$$= max[0, x_2 - 0,0625 + 0] \tag{3.26}$$

and

$$C_2^- = max[0, (0,0547 - x_2) + C_1^-] \tag{3.27}$$

$$= max[0, (0,0547 - x_2) + 0,0105] \tag{3.28}$$

since $x_2 = 0,05250$, we obtain

$$C_2^+ = max[0, (0,05250 - 0,0625 + 0)] = 0 \tag{3.29}$$

and

$$C_2^- = max[0, (0,0547 - 0,05250 + 0,0105)] = 0,0127 \tag{3.30}$$

Panels (a) and (b) of table 3.5 summarize the remaining calculations. The quantities N^+ and N^- in table 3.5 indicate the number of consecutive periods that the cusums C_i^+ or C_i^- have been nonzero.

The tabular cusum also indicates when the shift probably occurred. The counter N^+ records the number of consecutive periods since the upper-side cusum C_i^+ rose above

Table 3.5
The tabular cusum for cusum example

		(a)			(b)		
Period i	x_i	$x_i - 0,0625$	C_i^+	N^+	$0,0547 - x_i$	C_i^-	N^-
1	0,04418	-0,01641	0	0	0,01243	-0,0105	1
2	0,0525	-0,00809	0	0	0,00411	-0,0127	2
3	0,04791	-0,01268	0	0	0,0087	-0,0195	3
4	0,05881	-0,00178	0	0	-0,0022	-0,0154	4
5	0,05766	-0,00293	0	0	-0,00105	-0,0125	5
6	0,06655	0,00596	0,0041	1	-0,00994	-0,0006	6
7	0,06024	-0,00035	0,0018	2	-0,00363	0	0
8	0,0634	0,00281	0,0027	3	-0,00679	0	0
9	0,06254	0,00195	0,0027	4	-0,00593	0	0
10	0,06569	0,0051	0,0059	5	-0,00908	0	0
11	0,06971	0,00912	0,0131	6	-0,0131	0	0
12	0,05422	-0,00637	0,0048	7	0,00239	-0,0005	1

the value of zero.

It is useful to present a graphical display for the tabular cusum. These charts are sometimes called cusum status charts. They are constructed by plotting C_i^+ and C_i^- versus the sample number. Figure 3.7 shows the cusum status chart for the data in our example.

Each vertical bar represents the value of C_i^+ and C_i^- in period i. With the decision interval plotted on the chart, the cusum status chart resembles a Shewhart control chart. We have also plotted the observations x_i for each period on the first cusum status chart as solid dots. This frequently helps the user of the control chart to visualize the actual process performance that has led to a particular value of the cusum. Some computer packages have implemented the cusum status chart. In some packages, for example in Minitab, the lower is defined as

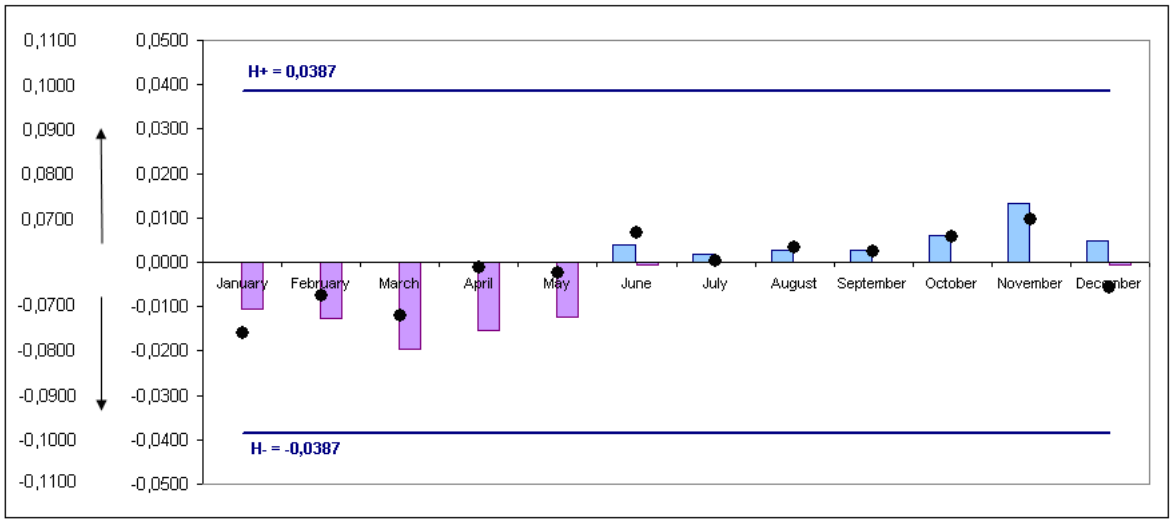


Figure 3.7 Cusum status charts - Manual chart

$$C_i^- = min[0, x_i - \mu_0 + k + C_{i-1}^-] \tag{3.31}$$

This results in a lower cusum that is always ≤ 0 (it is the negative of the lower cusum value from eq 3.31). Note in figure 3.8 that the values of the lower cusum range from 0 to -0,0387.

The action taken following an out-of-control scheme is identical to that with any control chart; the assignable cause should be searched for, any corrective action required must be taken and the cusum must be initialized again at zero. When the assignable cause has occurred, as we mentioned in the previous example, is determined by counting backward from the out-of-control signal to the time period when the cusum lifted above zero.

In situations where an adjustment to some manipulatable variable is required in order to bring the process back to the target value μ_0, it may be helpful to have an estimate of the new process mean following the shift. This can be computed from

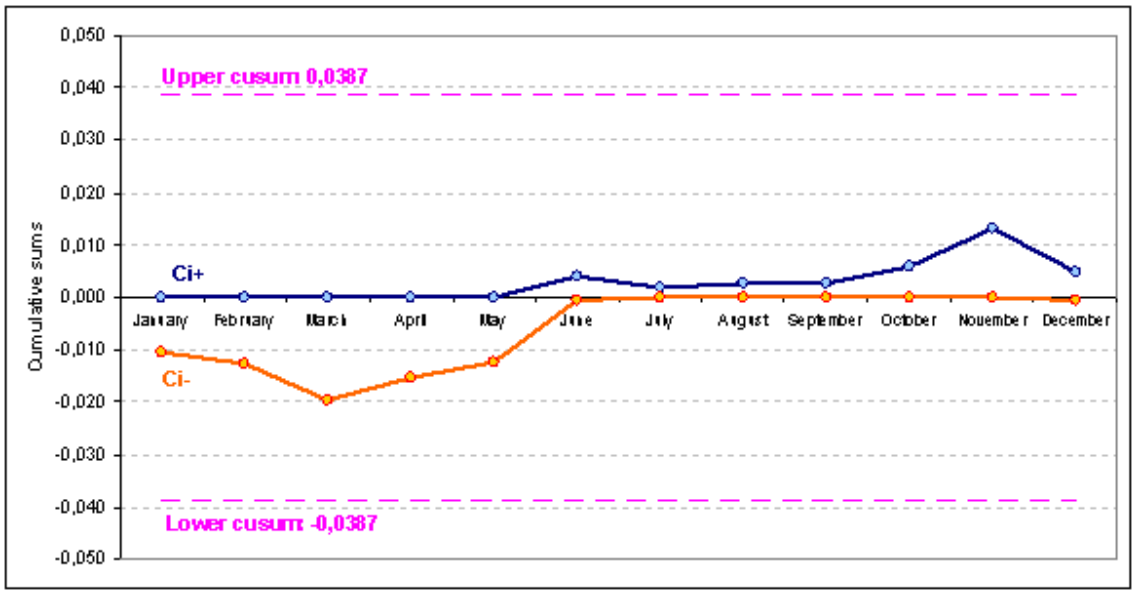


Figure 3.8 Cusum status charts - MS Excel chart

$$\hat{\mu} = \begin{cases} \mu_0 + K + \frac{C_i^+}{N^+} & \text{if } C_i^+ > H \\ \mu_0 - K - \frac{C_i^-}{N^-} & \text{if } C_i^- < H \end{cases} \tag{3.32}$$

To illustrate the use of equation, consider the cusum in period 9 with $C_9^+ = 0,0027$. From equation, we would estimate the new process mean average as

$$\begin{aligned} \hat{\mu} &= \mu_0 + K + \frac{C_9^+}{N^+} \\ &= 0,0586 + 0,00387 + \frac{0,0027}{4} \\ &= 0,0631 \end{aligned} \tag{3.33}$$

So, we would conclude that mean fraction of failures has shifted from 0,0586 to 0,0631, and would need to make an adjustment for the manipulatable variable that would result in moving the new mean down by 0,0045 units.

Finally, one should understand that runs tests, and other sensitizing rules such as the zone rules, can not be safely applied to the cusum, because successive values of C_i^+ and C_i^- are not independent. In fact, the cusum can be thought of as a weighted average, where the weights are stochastic or random [28].

3.3.4.3 Recommendations for Cusum Design. Before designing a tabular cusum, we should choose values for the reference value K and the decision interval H. It is usually recommended that these parameters be selected to provide good average run length performance. There have been many analytical studies of cusum Average Run Length (ARL) performance. Based on these studies, we may give some general recommendations for selecting K and H.

Define $H = h\sigma$ and $K = k\sigma$, where σ is the standard deviation of the sample variable used in forming the cusum. Using $h = 4$ or $h = 5$ and $k = 0,5$ will generally provide a cusum that has good ARL properties against a shift of about 1σ in the process mean [40]-[42].

To illustrate how well the recommendations of $h = 4$ or $h = 5$ and $k = 0,5$ will work, consider the two-sided average run lengths shown in table 3.6. Note that a 1σ shift would be detected in either 8,38 samples (with $k = 0,5$ and $h = 4$) or 10,4 samples (with $k = 0,5$ and $h = 5$). By comparison, a Shewart control chart for individual measurements would require 43,96 samples, on the average, to detect this shift.

Note also from table 3.6 that $h = 4$ results in an in-control $ARL_0 = 168$ samples, whereas $h = 4$ results in $ARL_0 = 465$ samples.If we choose $h = 4,77$, this will provide a cusum with $ARL_0 = 370$ samples, which matches the ARL_0 value for a Shewart control chart with the usual 3σ limits [28].

Generally, we want to choose k relative to the size of the shift we want to detect; that is, $k = \frac{1}{2}\delta$ where δ is the size of the shift in standard deviation units. This

Table 3.6
ARL Performance of the Tabular Cusum with k=0,5 and h=4 or h=5

Shift in mean (multiple of σ)	**h=4**	**h=5**
0	168	465
0,25	74,2	139
0,5	26,6	38
0,75	13,3	17
1	8,38	10,4
1,5	4,75	5,75
2	3,34	4,01
2,5	2,62	3,11
3	2,19	2,57
4	1,71	2,01

approach comes very close to minimizing the ARL_1 value for detecting a shift of size δ for fixed ARL_0. As we discussed earlier, a widely used value in practice is $k_0, 5$. Then, once k is selected, you should choose h to give the desired in-control ARL_0 performance. Hawkins gives a table of k values and the corresponding h values that will achieve $ARL_0 = 370$. These are reproduced in table 3.7.

Table 3.7
Values of k and the Corresponding Values of h That Give $ARL_0 = 370$ for the Two-Sided Cusum [43]

k	0,25	0,5	0,75	1	1,25	1,5
h	8,01	4,77	3,34	2,52	1,99	1,61

What can be done to improve the cusum design performance and cusum responsiveness for large shifts and how these approaches can be combined with this study will be discussed later in the discussion part.

Thus far, in the previous chapters, quality in healthcare, performance measurement, statistical process control theory and tools were discussed. Further on, the data analysis part will be explained.

4. DATA ANALYSIS

In data analysis part, definitions of the chosen KPI, how they are calculated, which SPC tool is used to analyze them and how the computer program is developed will be explained.

4.1 Key Performance Indicators

As mentioned earlier, KPI are critical measurements of the performance of essential tasks, operations, or processes. A KPI will usually unambiguously reveal conditions or performance that is outside the norm and that signals a need for managerial intervention.

In this study, we chose 8 performance indicators based on the data available from the maintenance, repair, equipment and stock management software package MAESTRO, in V.K.V. Amerikan Hastanesi, Istanbul.

KPI 1 - Average Response Time

Average response time is the average time interval in minutes between the initial notification of a failure order and the time the technician arrives on site. It is calculated by subtracting the notification time from the arrival time of the technician and taking the averages of these values according to the chosen monitoring time frequency, yearly, monthly or weekly.

$$ART(m) = Arrival\,time\,of\,technician(m) - Notification\,time\,of\,order(m) \quad (4.1)$$

Normally, response times should be as fast as possible but it can vary significantly due to if the work ordered is an in-house repair or not, the time of the failure, or steeply even the traffic conditions. Since fast response times increase the customer sat-

isfaction, this metric (indicator) is useful for short term monitoring as well establishing long-term performance trends [44].

KPI 2 - Average Repair Time

Total repair time is the time interval in minutes between the beginning and at the end of the repair. Dividing the total repair time (measured in labor minutes) by total number of repairs performed gives the average number of minutes of work, called the average repair time.

$$Average\,Repair\,Time(m) = \frac{Total\,Repair\,Time(m)}{Total\,Number\,of\,Repairs} \tag{4.2}$$

With this parameter; it is possible to determine the equipment that exceeds the estimated repair time limits, low quality equipment and inadequately educated technicians.

For a desired goal of minimum repair time, as the average repair time increases, pressure will rise within the system to add more personnel in order to increase maintenance capacity. Since increases in average repair time are quickly apparent, a rise in the repair time often results in corrective action within a week or two [45].

KPI 3 - Average In-house Repair Time

Average in-house repair time is calculated by narrowing down the time limit (in labor minutes) for total repair times. It is assumed that performed repairs that takes up 7 workdays (10080 labor minutes) are in-house repairs. Dividing the total in-house repair time (measured in labor minutes) by total number of in-house repairs performed gives the average number of minutes of in-house work, called the average in-house repair time. Like in Average Repair Time, the goal is to minimize the in-house repair times.

$$Average\,In-house\,Repair\,Time(m) = \frac{Total\,In-house\,Repair\,Time(m)}{Total Number\,of\,In-house\,Repairs} \quad (4.3)$$

With the program developed, Average Response Time (KPI 1), Average Repair Time (KPI 2) and Average In-house Repair Times (KPI 3) can be analyzed by using SPC tools X control chart and cusum chart and can be monitored yearly, monthly and weekly, also per employee by employee or for the whole biomedical/clinical engineering department.

KPI 4 - Total Cost per Repair (TL)

Total Cost per Repair is a strong indicator that demonstrates cost effectiveness for biomedical/clinical engineering departments in hospitals. The desired goal is to keep the costs at minimum. Total cost is calculated by summing spare parts, labor and service costs up.

$$Total\,Cost\,for\,Repair = Spare\,Part\,Costs + Labor\,Costs + Service\,Costs \quad (4.4)$$

We planned to analyze spare part costs, labor costs, service costs and total costs of the device failures. Since users of maintenance, repair, equipment and stock management database (MAESTRO) in the hospital has only entered the data of labor costs of device failures, the total costs section reflects only the labor costs. However, we wrote our software program assuming the staff would enter the data separately for each defined type of cost. This means, if the staff starts to enter qualified data, our program will also show it without making any difference on the codes.

Costs can be analyzed by using SPC tools X control chart and cusum chart and can be monitored yearly and monthly for the whole medical device park or for a specific device and for each department or for a specific department in hospital.

KPI 5 - Fraction of Failures

Fraction of failures is a fraction that take place in the hospital or in a specific department within a time interval. It is calculated by dividing the total number of failures by total number of medical devices hospital - wide (or in a specific department).

$$Fraction\,of\,Failures = \frac{Total\,Number\,of\,Failures}{TotalNumber\,of\,Medical\,Devices} \tag{4.5}$$

Fraction of failures can be very serviceable to see "the needs" of the equipment and the departments in the hospital and to establish the work plan. This metric can be analyzed monthly, for hospital-wide, departmentally and per devices by device by using SPC tools x control chart and cusum chart with the developed program.

KPI 6 - Total Maintenance Rate

The possibility of preventing breakdowns and failures of medical technologies is guaranteed by the periodic check on their well-functioning. So, the main objective of a preventive maintenance (PM) program is to reduce the risk of injury or unfavorable impact on patient care and also on operative staff and to decrease equipment life cycle costs. Gradual equipment deterioration without maintenance and calibration may bring the safety level below an acceptable level of manageable risk, also referred to the difficulties of reducing user injuries [46]. To comply with such a mature clinical engineering work plan is a measure of development and efficiency [47].

Total maintenance rate is the total number of calibrations, preventive and regular maintenances performed monthly against the number of medical devices for hospital wide. It can be analyzed and monitored by using SPC tools x control chart and cusum chart for hospital-wide monthly.

$$Total\ Maintenance\ Rate = \frac{Calibrated\ \&\ Maintained\ number\ of\ devices}{Total Number\ of\ Medical\ Devices} \tag{4.6}$$

Although we analyzed Total Maintenance Rate, we find it necessary to analyze Uncompleted Calibration Preventive Maintenance Rates separately, too.

KPI 7 - Uncompleted Calibration Rate

Uncompleted calibration rate is the number of uncompleted medical device calibrations performed against those scheduled on the maintenance, repair, equipment and stock management database (MAESTRO) for hospital-wide. Since the calibration programs are available monthly, this indicator can be only monitored monthly.

$$Uncompleted Calibration\ Rate = \frac{Planned - Calibrated\ number\ of\ devices}{Planned\ number\ of\ devices} \tag{4.7}$$

KPI 8 - Uncompleted Preventive Maintenance Rate

Uncompleted preventive maintenance rate is the number of medical devices not maintained against those scheduled on the maintenance, repair, equipment and stock management database (MAESTRO) for hospital-wide. Like calibration programs, the preventive maintenance programs are only available monthly and thus Uncompleted Preventive Maintenance Rate can also be monitored monthly.

$$Uncompleted\ Preventive\ Maintenance\ Rate = \frac{Planned - Maintained\ number\ of\ devices}{Planned\ number\ of\ devices} \tag{4.8}$$

With the program developed, all these "rates"; Uncompleted Calibration Rate (KPI 7) and Uncompleted Preventive Maintenance Rate (KPI 8) can be analyzed and monitored by using SPC tools p control chart and cusum chart for hospital-wide monthly.

These all 8 indicators were measured in the following 39 departments, namely Coronary Intensive Care, Invasive Cardiology, Neonatal Intensive Care, Nursery, Operation Room, General Intensive Care, Cardiovascular Surgery, Cardiovascular Surgery Intensive Care, Blood Bank, Pediatrics, Ear - Nose - Throat (Otorhinolaryngology), Cardiology, Nuclear Medicine, Nutrition and Diet, Check Up, Oncology, Plastics and Reconstructive Surgery, Medical Imaging, Dermatology, Orthopedics and Traumatology, Physical Therapy and Rehabilitation, Molecular and Genetics Laboratory, Internal Medicine, Urology, Women's Health Center, Embryology, Gastroenterology, General Surgery, Endocrinology, Hand and Reconstructive Microsurgery, Neurology, Neurosurgery, Ophthalmology, Respiration Care, Thoracic Diseases and Surgery, Clinical Laboratory, Emergency Laboratory, Emergency Service and Pharmacy.

The chosen device types for some of the KPI are namely Crash cards, Act devices, Open beds, Patient-Controlled Analgesia (PCA) Pumps, Plaster saws, Allergy Testing devices, Operating tables, Anesthesia devices, Anesthesia Filtration Pumps, Angiography device, Angio/MR/CT injectors, Argon devices, Archiving system, Arthroscopy Pumps, Arthrosporic shavers, Aspirators, Patient Raise tables, Baby scales, Computerized tomography, Bilirubin meters, Bipap devices, Biomicroscopes, Cervical seats, Steam autoclaves, Bronchoscopes, Surgical saws, Chart projectors, Skin cancer detection system, CO2 and heat measurement test device, CPM (continuous passive motion) devices, Computerized Digital Radiography (CR) devices, CR printers, Defibrillators, Deionized Water devices, Dermatoscopes, Diadynamics, Digital Camera Units, Dynamometers, Diathermy devices, Birth tables, Dopplers, Down Syndrome test device, Dose Calibrators, Dosimeters, Duodenescopes, DVD Recorders, Dye Lasers (dermatological), EECP devices, EEG devices, Exercise ECG (Stress Test), Exercisers, Cross trainers, Exercise stairs, Exercise mats, Exercise system, ECG devices, ECG, holters, ECHO (Echocardiography) devices, Electrophoresis devices, Electrocoters,

Electrotherapy units, Elisa devices, Embryo freezing devices, EMG devices, Endoscopy system processor, Ethylene Oxide dedectors, Ethylene Oxide devices, Ethylene Oxide drying cabinets, Drying ovens, Phacometers, Fetal Monitors, Fibrillation devices, Film developing machines, Physical Therapy tables, Physical Therapy Ultrasounds, Fluidotherapy, Phoropters, Photometer devices, Phototherapy devices, Fundus, Gamma cameras, Gamma probes, Gastroscope, Geiger Müller, Vision testing devices, External pacemakers, Assay balances, Patient beds, Patient monitors, Air compressors, Air bed motors, Head lights, Hematology analyzers, Hemodymanic monitors, Hemodialysis devices, Hemofiltration devices, Hemoglobin analyzers, Holmium laser devices, Holter devices, Hot bag boilers, Hot plates, Hybrite devices, IABPs, Immunotest analyzers, Indirect ophthalmoscopes, Heaters, Light sources, Urine analyzers, Infusion pumps, Incubators, Hearing test devices, Gel imaging devices, Heart lung machine, Phlebotomy chairs, Phlebotomy/shaker devices, Blood gas devices, Blood warmers, Blood culture devices, Blood cell count devices, Blood compression devices, Capnographs, Carbon devices, Carbondioxide monitors, Carbondioxide pumps, Bone densitometry, Keratometer, Short Wave Diathermy, Weight Height analyzers, Coagulation devices, Colonoscopes, Colposcopes, Treadmills, Cryo devices, Drying cabinets, Culture antibiogram devices, Laminar Flowmeter units, Larengoscopes, Laser devices, Lift devices, Limelight Lasers, Liposuction devices, Breast pumps, Mammography device, Massage devices, Medical purpose monitors, Medical purpose printers, Medical purpose refrigerators, Central monitors, Microscopes, Mobile X-rays, MRI, MR compatible monitors, Consultation chairs, Consultation lamps, Consultation tables, Navigation system, Nebulizators, Negatoscopes, Ovens, Odiometers, Ophtalmascope/Otoscope, Ophtalmic Cameras, Ophtalmascopes, Operating Lamps, Otoanalyzers, Autoclaves (Flash), Autotransfusion devices, Osmometers, Package sealing devices, Pachimeters, Pulseoximeters, Medicine trolleys, Paraffin boilers, Parallel bars, Finger stairs, Pathology devices, Perfusors, Perimeters, Peristaltic pumps, Pet CT, Ph meters, Pipettes, Plasma sterilizators, Puva devices, Radiation monitors, Refractometers, RF devices, Rhinoscopes, Rotators, Radioscopes, Centrifuges, Sedimentation devices, Strechers, Serum warmers, Silent cabinets, Neurofeedback device, Sinoptophors, Scopies, Cold light sources, Cooling compression devices, Somnoplasty devices, Spectrophotometers, Sphinctometers, Spirometers, Steppers, Sternum saws, Water Calorics Stimulators, Glucose measure-

ment devices, T-wave alternans devices, Sphygmomanometers, Sphygmomanometer holters, Scales, Wheel chairs, Tele holters, Telemetry systems, Tens devices, Thermal Blocks, Thermal Cyclers, Thermometers, Tilt tables, Tonometers, Trivex systems, Trombophoresis devices, Platelet agitators, Tube sealing devices, Ultrasounds, Ultrasonic aspirators, Ultrasonic washers, Urodynamic devices, Uroflowmeter Systems, Vacuum units, Vaporizators, Ventilators, Video recorders, Vortex devices, Body fat analyzers, Wavescans, Workstations, Washing machines and Non-medical devices - Test devices.

All Key Performance Indicators, as mentioned earlier, were modeled with discussed SPC tools in MS Excel before designing the software to monitor the data quality and to make some interpretations.

5. THE SOFTWARE

As we have mentioned in the introduction part, the primary goal of this study is to design and develop a software package program for biomedical/clinical engineering departments to monitor, control and improve implementation of different performance indicators which were discussed above. In this chapter, how we chose the programming language, how the developed software program can be used and the special features of the program will be explained.

5.1 The Programming Language

Every platform, framework, and architecture has its own strengths and weaknesses. The reason we choose .NET Framework to write our code with, is the advantages it offers to developers.

Consistent Programming Model

Different programming languages have different approaches for doing a task. When using different programming languages, a disparity exists among the approach developers use to perform the task. The difference in techniques comes from how different languages interact with the underlying system that applications rely on.

With .NET, there's a unified means of accomplishing the same task by using the .NET Class Library, a key component of the .NET Framework. The functionality that the .NET Class Library provides is available to all .NET languages resulting in a consistent object model regardless of the programming language the developer uses.

Direct Support for Security

With .NET, the Framework enables the developer and the system administrator

to specify method level security. It uses industry-standard protocols such as TCP/IP, XML, SOAP and HTTP to facilitate distributed application communications. This makes distributed computing more secure because .NET developers cooperate with network security devices instead of working around their security limitations.

Simplified Development Efforts

The .NET Framework simplify development by separating the application logic and presentation logic making it easier to maintain the code.

Another advantage of creating applications is debugging. Visual Studio .NET and other third party providers provide several debugging tools that simplify application development. The .NET Framework simplifies debugging with support for Runtime diagnostics. Runtime diagnostics helps you to track down bugs and also helps you to determine how well an application performs. The .NET Framework provides three types of Runtime diagnostics: Event Logging, Performance Counters and Tracing.

Easy Application Deployment and Maintenance

The .NET Framework makes it easy to deploy applications. It handles the details of locating and loading the components an application needs, even if several versions of the same application exist on the target computer. The .NET Framework ensures that all the components the application depends on are available on the computer before the application begins to execute [48].

Deciding with which programming language the code will be written is an another challenging period of tense search. At the end of this period we designated two possible programming languages that we can use; C# and Visual Basic (VB). Of course, there are other .NET languages available, too. At first sight, C++ seemed the most attractive choice for me as I have some previous experience of that language. But we learned that the .NET version of C++ is best used for manipulating unmanaged memory. In most cases, C# would be a better choice of .NET language for a program-

mer with C++ experience. Unlike C++, the C# language was specifically designed for the .NET Framework. It benefits from a simple syntax, garbage collection and type safety to eliminate many potential bugs.

When evaluating programming languages for .NET, the choice between C# and VB is largely a matter of personal preference. In the past, VB may have been considered to be inherently less powerful than other general purpose languages. But VB.NET is altogether a different beast from VB 6. It is every bit as powerful as C#, it has full access to the .NET Framework and its compiled applications should generally be just as fast and efficient as similar applications written in C# [49].

The only major difference between the two languages is that C# can break out of the 'managed' world of .NET to support unsafe code should this be required. Explicit use of pointers is seldom required when programming .NET. Since I can not do without pointers, then C# is the right choice of language for me. But for some one who is familiar to work within the managed world of .NET, then C# or VB will be equally suitable.

System Requirements:

We designed our software program to work with MS Windows XP or higher with .NET Framework 3.5. As MS Windows XP's system requirements are lower than .NET Framework 3.5's system requirements, and our software does not need anything on its own except from .NET Framework 3.5, we determined our program's system requirements same as .NET Framework 3.5's.

.NET Framework 3.5 requires 96 MB RAM minimum, 256 MB recommended, 400 MHz Pentium processor or equivalent minimum, 1GHz Pentium processor or equivalent recommended, up to 500 MB of available hard disk space, 1280×720, 256 colors minimum or 1600×12004 true color display recommended. It does not require CD or DVD drive, so does our program.

5.2 Data Input

The data for this study was obtained from the Maintenance, Repair, Equipment and Stock Management software, MAESTRO, in the Biomedical/clinical engineering department at V.K.V. Amerikan Hastanesi, in Istanbul.

MAESTRO is a product of Tacosoft Internet & Computer Software Company. MAESTRO, which used in hotels, business centers, factories and hospitals, organizes the whole maintenance, repair and control actions, thus becomes essential for technical, housekeeping and/or biomedical/clinical engineering departments.

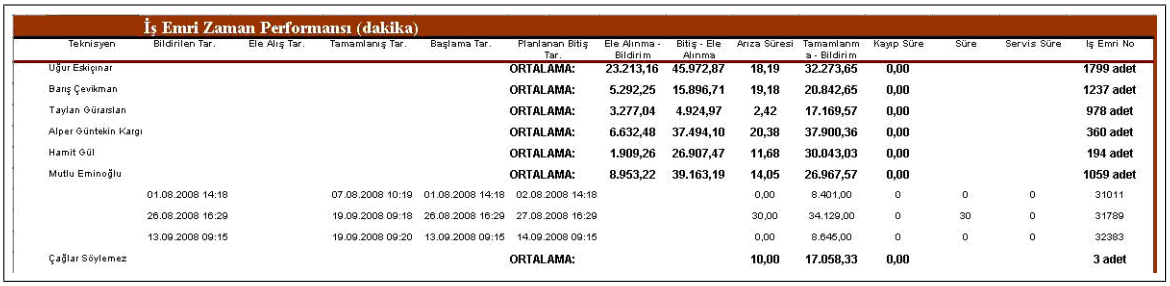
In V.K.V. Amerikan Hastanesi, this software package is being used not only for biomedical/clinical engineering department but also for the other technical departments. Since it is not possible to monitor the performance in a short time, we decided to use the data collected and available in MAESTRO and determined our KPI according to them. We did not find it ethical to get the whole MAESTRO database from the hospital or from the software company with or without permission. So, we exported the data from MAESTRO in the form of MS Excel data reports, which is a special feature of itself.

The reports to be exported were determined by our defined KPI. The reports are namely: Maintenance and Repair Times, Total Completed Tasks, Failure Reports by Department, Failure Reports by Device, Total Device Count for Department, Total Device Count and Monthly Calibration and Maintenance Plans.

Maintenance and Repair Times:

This report shows the employees of the biomedical/clinical engineering department, their work order counts, when they respond to work orders, when they start to deal with a work order and when they finish. All these metrics are also available as sums for the whole biomedical/clinical engineering department. As can be seen below, it also includes some calculations, too. We used this report to calculate directly KPI 1 -

Average Response Times, KPI 2 - Average Repair Times and KPI 3 - Average In-house Repair Times.



İş Emri Zaman Performansı (dakika)

Teknisyen	Bildirilen Tar.	Ele Alış Tar.	Tamamlanış Tar.	Başlama Tar.	Planlanan Bitiş Tar.	Ele Alınma - Bildirim	Bitiş - Ele Alınma	Arıza Süresi	Tamamlanma - Bildirim	Kayıp Süre	Süre	Servis Süre	İş Emri No
Uğur Eskiçınar					**ORTALAMA:**	**23.213,16**	**45.972,87**	**18,19**	**32.273,65**	**0,00**			**1799 adet**
Barış Çevikman					**ORTALAMA:**	**5.292,25**	**15.896,71**	**19,18**	**20.842,65**	**0,00**			**1237 adet**
Taylan Güranslan					**ORTALAMA:**	**3.277,04**	**4.924,97**	**2,42**	**17.169,57**	**0,00**			**978 adet**
Alper Güntekin Kargı					**ORTALAMA:**	**6.632,48**	**37.494,10**	**20,38**	**37.900,36**	**0,00**			**360 adet**
Hamit Gül					**ORTALAMA:**	**1.909,26**	**26.907,47**	**11,68**	**30.043,03**	**0,00**			**194 adet**
Mutlu Eminoğlu					**ORTALAMA:**	**8.953,22**	**39.163,19**	**14,05**	**26.967,57**	**0,00**			**1059 adet**
	01.08.2008 14:18		07.08.2008 10:19	01.08.2008 14:18	02.08.2008 14:18			0,00	8.401,00	0	0	0	31011
	26.08.2008 16:29		19.09.2008 09:18	26.08.2008 16:29	27.08.2008 16:29			30,00	34.129,00	0	30	0	31789
	13.09.2008 09:15		19.09.2008 09:20	13.09.2008 09:15	14.09.2008 09:15			0,00	8.645,00	0	0	0	32383
Çağlar Söylemez					**ORTALAMA:**			**10,00**	**17.058,33**	**0,00**			**3 adet**

Figure 5.1 Maintenance and Repair Times Report

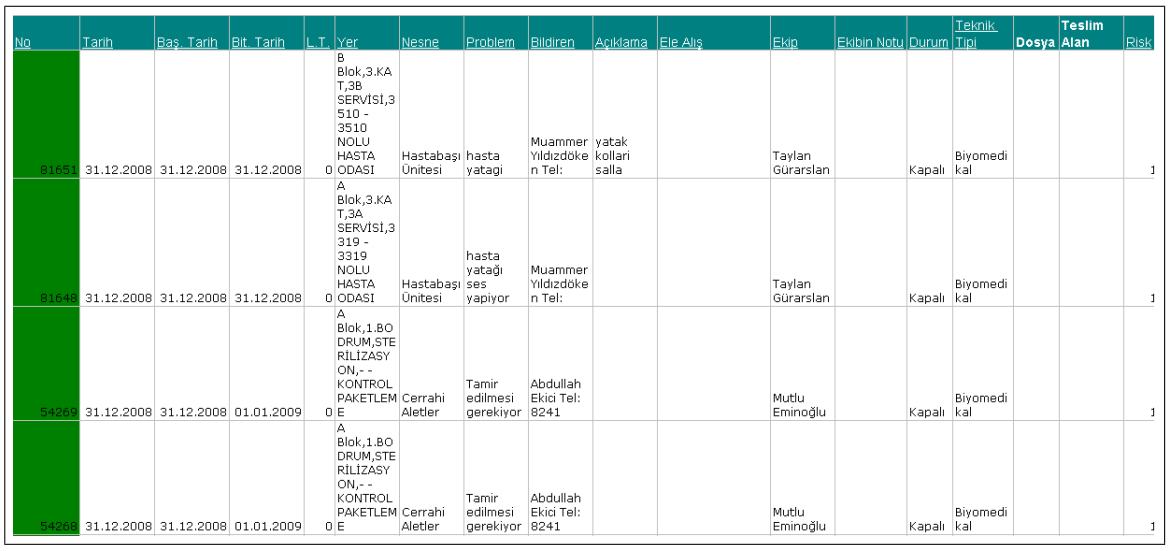
Total Completed Tasks:

This report shows all the closed work orders, "total completed tasks", between chosen dates. Since data is only available for 2008, we filtered the report from 01.01.2008 to 31.12.2008. It has the information of order number, order date, when the technician starts to deal with the order and finishes it, from which department the order is entered and who has entered the order, with which device the problem occurs, what the problem is and comments about the problem, the response time of the order, who responses the order, technical type of the order, if the order is open or closed and the risk of the problem.

We used this report to calculate the total number of failures in hospital-wide for KPI 5 - Fraction of failures; and to calculate total devices that has calibration and preventive maintenance in KPI 6 - Total Maintenance Rate, KPI 7 - Calibration Completion Rate and KPI 8 - Uncompleted Preventive Maintenance Rate.

Failure Reports by Department:

This report shows how many medical device breakdowns has occurred, in which department they have occurred and how much these breakdown's repairs cost. Failure



No	Tarih	Baş. Tarih	Bit. Tarih	L.T.	Yer	Nesne	Problem	Bildiren	Açıklama	Ele Alış	Ekip	Ekibin Notu	Durum	Teknik Tipi	Dosya	Teslim Alan	Risk
81651	31.12.2008	31.12.2008	31.12.2008	0	B Blok,3.KAT,3B SERVİSİ,3510 - 3510 NOLU HASTA ODASI	Hastabaşı Ünitesi	hasta yatagi	Muammer Yıldızdöken Tel:	yatak kollari salla		Taylan Gürarslan		Kapalı	Biyomedikal			1
81648	31.12.2008	31.12.2008	31.12.2008	0	A Blok,3.KAT,3A SERVİSİ,3319 - 3319 NOLU HASTA ODASI	Hastabaşı Ünitesi	hasta yatağı ses yapiyor	Muammer Yıldızdöken Tel:			Taylan Gürarslan		Kapalı	Biyomedikal			1
54269	31.12.2008	31.12.2008	01.01.2009	0	A Blok,1.BODRUM,STERİLİZASYON,- - KONTROL PAKETLEME	Cerrahi Aletler	Tamir edilmesi gerekiyor	Abdullah Ekici Tel: 8241			Mutlu Eminoğlu		Kapalı	Biyomedikal			1
54268	31.12.2008	31.12.2008	01.01.2009	0	A Blok,1.BODRUM,STERİLİZASYON,- - KONTROL PAKETLEME	Cerrahi Aletler	Tamir edilmesi gerekiyor	Abdullah Ekici Tel: 8241			Mutlu Eminoğlu		Kapalı	Biyomedikal			1

Figure 5.2 Total Completed Tasks Report

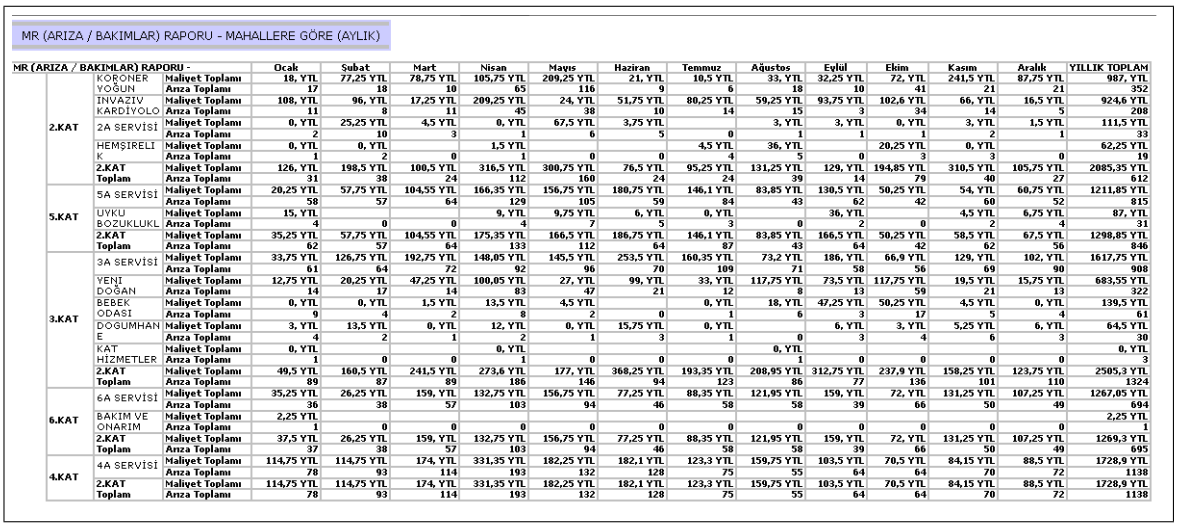
reports for department can be generated once at the end of the year since it gives annual information. We also generated this report for 2008.

We used this report directly to display Repair costs for departments in KPI 4 - Total Cost per Repair and to calculate "total number of failures" in departments in KPI 5 - Fraction of failures.

Failure Reports by Device:

This report shows which medical device has a breakdown, location of the broken device, who handled it, if the work order is open or closed and the cost of the breakdown's repair. Unlike the failure reports by department, this report can be generated separately for every month. We generated this report from January 2008 to December 2008.

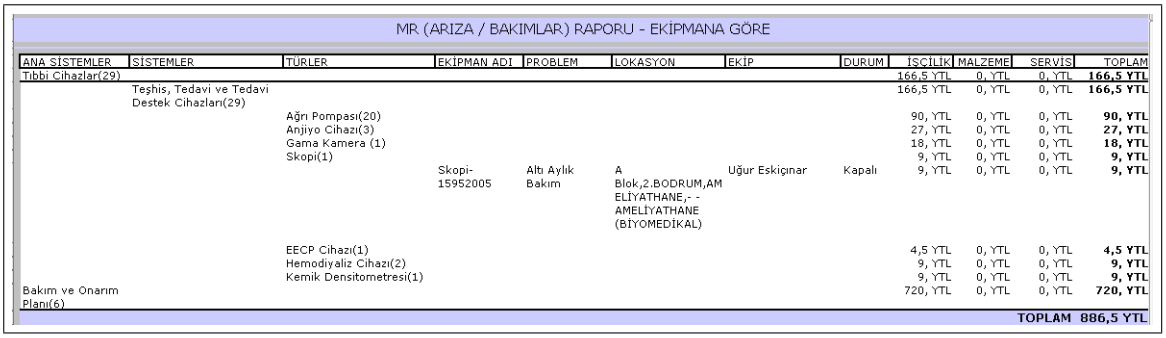
We used this report directly to display Repair costs for devices in KPI 4 - Total Cost per Repair and to calculate "total number of failures" of devices in KPI 5 - Fraction of failures.



MR (ARIZA / BAKIMLAR) RAPORU - MAHALLERE GÖRE (AYLIK)

MR (ARIZA / BAKIMLAR) RAPORU -			Ocak	Subat	Mart	Nisan	Mayıs	Haziran	Temmuz	Ağustos	Eylül	Ekim	Kasım	Aralık	YILLIK TOPLAM
	KORONER	Maliyet Toplamı	18, YTL	77,25 YTL	78,75 YTL	105,75 YTL	209,25 YTL	21, YTL	10,5 YTL	33, YTL	32,25 YTL	72, YTL	241,5 YTL	87,75 YTL	987, YTL
	YOĞUN	Arıza Toplamı	17	18	10	65	116	9	6	18	10	41	21	21	352
	INVAZIV	Maliyet Toplamı	108, YTL	96, YTL	17,25 YTL	209,25 YTL	24, YTL	51,75 YTL	80,25 YTL	59,25 YTL	93,75 YTL	102,6 YTL	66, YTL	16,5 YTL	924,6 YTL
	KARDİYOLO	Arıza Toplamı	11	8	11	45	38	10	14	15	3	34	14	5	208
2.KAT	2A SERVİSİ	Maliyet Toplamı	0, YTL	25,25 YTL	4,5 YTL	0, YTL	67,5 YTL	3,75 YTL		3, YTL	3, YTL	0, YTL	3, YTL	1,5 YTL	111,5 YTL
		Arıza Toplamı	2	10	3	1	6	5	0	1	1	1	2	1	33
	HEMŞİRELİ	Maliyet Toplamı	0, YTL	0, YTL		1,5 YTL			4,5 YTL	36, YTL		20,25 YTL	0, YTL		62,25 YTL
	K	Arıza Toplamı	1	2	0	1	0	0	4	5	0	3	3	0	19
	2.KAT	Maliyet Toplamı	126, YTL	198,5 YTL	100,5 YTL	316,5 YTL	300,75 YTL	76,5 YTL	95,25 YTL	131,25 YTL	129, YTL	194,85 YTL	310,5 YTL	105,75 YTL	2085,35 YTL
	Toplam	Arıza Toplamı	31	38	24	112	160	24	24	39	14	79	40	27	612
	5A SERVİSİ	Maliyet Toplamı	20,25 YTL	57,75 YTL	104,55 YTL	166,35 YTL	156,75 YTL	180,75 YTL	146,1 YTL	83,85 YTL	130,5 YTL	50,25 YTL	54, YTL	60,75 YTL	1211,85 YTL
		Arıza Toplamı	58	57	64	129	105	59	84	43	62	42	60	52	815
5.KAT	UYKU	Maliyet Toplamı	15, YTL			9, YTL	9,75 YTL	6, YTL	0, YTL		36, YTL		4,5 YTL	6,75 YTL	87, YTL
	BOZUKLUKL	Arıza Toplamı	4	0	0	4	7	5	3	0	2	0	2	4	31
	2.KAT	Maliyet Toplamı	35,25 YTL	57,75 YTL	104,55 YTL	175,35 YTL	166,5 YTL	186,75 YTL	146,1 YTL	83,85 YTL	166,5 YTL	50,25 YTL	58,5 YTL	67,5 YTL	1298,85 YTL
	Toplam	Arıza Toplamı	62	57	64	133	112	64	87	43	64	42	62	56	846
	3A SERVİSİ	Maliyet Toplamı	33,75 YTL	126,75 YTL	192,75 YTL	148,05 YTL	145,5 YTL	253,5 YTL	160,35 YTL	73,2 YTL	186, YTL	66,9 YTL	129, YTL	102, YTL	1617,75 YTL
		Arıza Toplamı	61	64	72	92	96	70	109	71	58	56	69	90	908
	YENİ	Maliyet Toplamı	12,75 YTL	20,25 YTL	47,25 YTL	100,05 YTL	27, YTL	99, YTL	33, YTL	117,75 YTL	73,5 YTL	117,75 YTL	19,5 YTL	15,75 YTL	683,55 YTL
	DOĞAN	Arıza Toplamı	14	17	14	83	47	21	12	8	13	59	21	13	322
	BEBEK	Maliyet Toplamı	0, YTL	0, YTL	1,5 YTL	13,5 YTL	4,5 YTL		0, YTL	18, YTL	47,25 YTL	50,25 YTL	4,5 YTL	0, YTL	139,5 YTL
3.KAT	ODASI	Arıza Toplamı	9	4	2	8	2	0	1	6	3	17	5	4	61
	DOĞUMHAN	Maliyet Toplamı	3, YTL	13,5 YTL	0, YTL	12, YTL	0, YTL	15,75 YTL	0, YTL		6, YTL	3, YTL	5,25 YTL	6, YTL	64,5 YTL
	E	Arıza Toplamı	4	2	1	2	1	3	1	0	3	4	6	3	30
	KAT	Maliyet Toplamı	0, YTL			0, YTL				0, YTL					0, YTL
	HİZMETLER	Arıza Toplamı	1	0	0	1	0	0	0	1	0	0	0	0	3
	2.KAT	Maliyet Toplamı	49,5 YTL	160,5 YTL	241,5 YTL	273,6 YTL	177, YTL	368,25 YTL	193,35 YTL	208,95 YTL	312,75 YTL	237,9 YTL	158,25 YTL	123,75 YTL	2505,3 YTL
	Toplam	Arıza Toplamı	89	87	89	186	146	94	123	86	77	136	101	110	1324
	6A SERVİSİ	Maliyet Toplamı	35,25 YTL	26,25 YTL	159, YTL	132,75 YTL	156,75 YTL	77,25 YTL	88,35 YTL	121,95 YTL	159, YTL	72, YTL	131,25 YTL	107,25 YTL	1267,05 YTL
		Arıza Toplamı	36	38	57	103	94	46	58	58	39	66	50	49	694
6.KAT	BAKIM VE ONARIM	Maliyet Toplamı	2,25 YTL												2,25 YTL
		Arıza Toplamı	1	0	0	0	0	0	0	0	0	0	0	0	1
	2.KAT	Maliyet Toplamı	37,5 YTL	26,25 YTL	159, YTL	132,75 YTL	156,75 YTL	77,25 YTL	88,35 YTL	121,95 YTL	159, YTL	72, YTL	131,25 YTL	107,25 YTL	1269,3 YTL
	Toplam	Arıza Toplamı	37	38	57	103	94	46	58	58	39	66	50	49	695
	4A SERVİSİ	Maliyet Toplamı	114,75 YTL	114,75 YTL	174, YTL	331,35 YTL	182,25 YTL	182,1 YTL	123,3 YTL	159,75 YTL	103,5 YTL	70,5 YTL	84,15 YTL	88,5 YTL	1728,9 YTL
		Arıza Toplamı	78	93	114	193	132	128	75	55	64	64	70	72	1138
4.KAT	2.KAT	Maliyet Toplamı	114,75 YTL	114,75 YTL	174, YTL	331,35 YTL	182,25 YTL	182,1 YTL	123,3 YTL	159,75 YTL	103,5 YTL	70,5 YTL	84,15 YTL	88,5 YTL	1728,9 YTL
	Toplam	Arıza Toplamı	78	93	114	193	132	128	75	55	64	64	70	72	1138

Figure 5.3 Failure Reports by department



MR (ARIZA / BAKIMLAR) RAPORU - EKİPMANA GÖRE

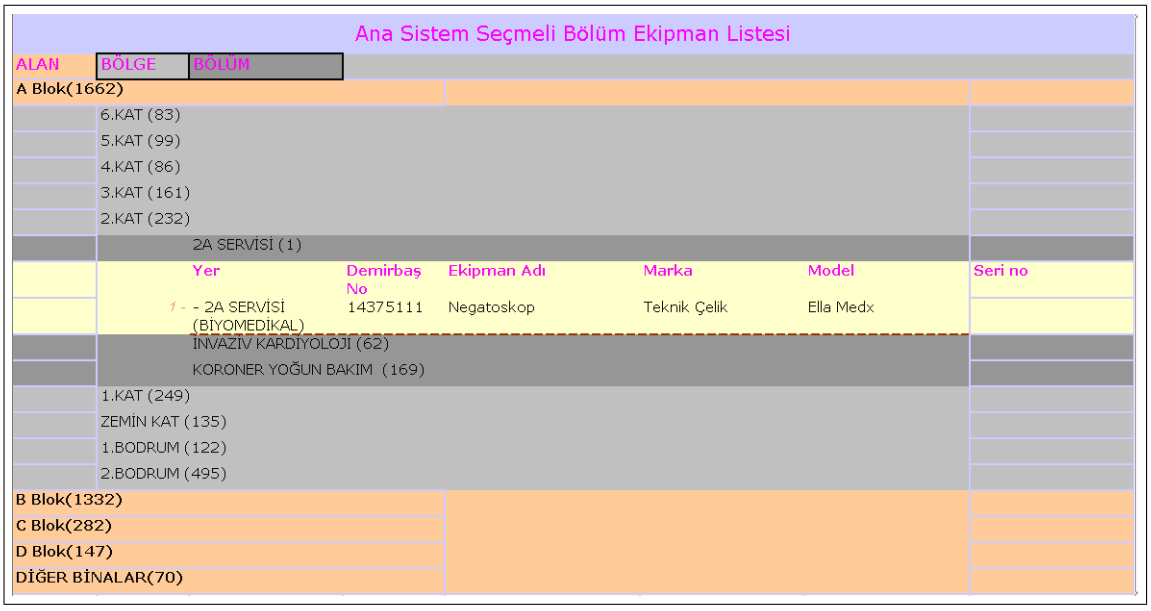
ANA SİSTEMLER	SİSTEMLER	TÜRLER	EKİPMAN ADI	PROBLEM	LOKASYON	EKİP	DURUM	İŞÇİLİK	MALZEME	SERVİS	TOPLAM
Tıbbi Cihazlar(29)								166,5 YTL	0, YTL	0, YTL	**166,5 YTL**
	Teşhis, Tedavi ve Tedavi Destek Cihazları(29)							166,5 YTL	0, YTL	0, YTL	**166,5 YTL**
		Ağrı Pompası(20)						90, YTL	0, YTL	0, YTL	**90, YTL**
		Anjiyo Cihazı(3)						27, YTL	0, YTL	0, YTL	**27, YTL**
		Gama Kamera (1)						18, YTL	0, YTL	0, YTL	**18, YTL**
		Skopi(1)						9, YTL	0, YTL	0, YTL	**9, YTL**
			Skopi-15952005	Altı Aylık Bakım	A Blok,2.BODRUM,AMELİYATHANE,- - AMELİYATHANE (BİYOMEDİKAL)	Uğur Eskiçınar	Kapalı	9, YTL	0, YTL	0, YTL	**9, YTL**
		EECP Cihazı(1)						4,5 YTL	0, YTL	0, YTL	**4,5 YTL**
		Hemodiyaliz Cihazı(2)						9, YTL	0, YTL	0, YTL	**9, YTL**
		Kemik Densitometresi(1)						9, YTL	0, YTL	0, YTL	**9, YTL**
Bakım ve Onarım Planı(6)								720, YTL	0, YTL	0, YTL	**720, YTL**
										TOPLAM	**886,5 YTL**

Figure 5.4 Failure Report per device

Total Device Count for Department:

This report shows which medical device belongs to which department. It also shows the brand names, models, serial numbers and stock numbers of the devices.

We used this report to calculate the total device count for different departments for KPI 5 - Fraction of failures.



Ana Sistem Seçmeli Bölüm Ekipman Listesi

ALAN	BÖLGE	BÖLÜM	Yer	Demirbaş No	Ekipman Adı	Marka	Model	Seri no
A Blok(1662)								
	6.KAT (83)							
	5.KAT (99)							
	4.KAT (86)							
	3.KAT (161)							
	2.KAT (232)							
		2A SERVİSİ (1)						
			1 - 2A SERVİSİ (BİYOMEDİKAL)	14375111	Negatoskop	Teknik Çelik	Ella Medx	
		İNVAZİV KARDİYOLOJİ (62)						
		KORONER YOĞUN BAKIM (169)						
	1.KAT (249)							
	ZEMİN KAT (135)							
	1.BODRUM (122)							
	2.BODRUM (495)							
B Blok(1332)								
C Blok(282)								
D Blok(147)								
DİĞER BİNALAR(70)								

Figure 5.5 Departmentally Total Device Counts Report

Total Device Count:

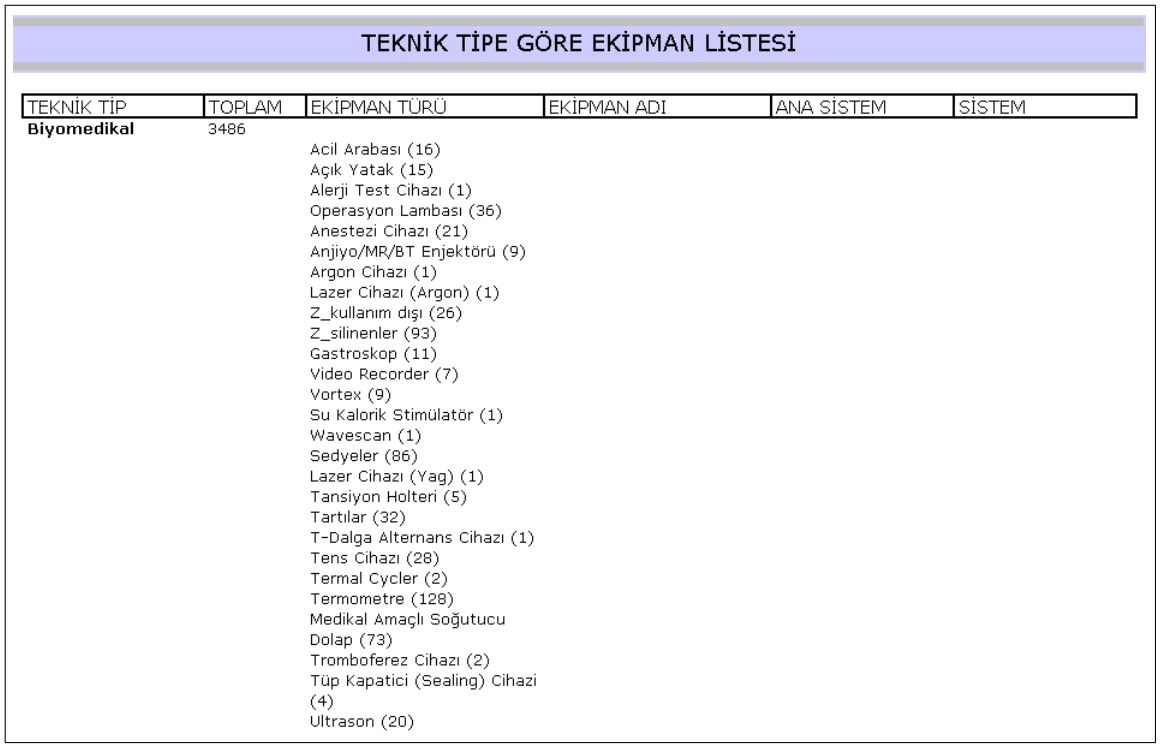
This report simply shows the possession of different technical departments together with biomedical/clinical engineering department. It gives the total counts for device types. We used this report to calculate the total device count for the whole hospital for KPI 5 - Fraction of failures.

Monthly Calibration and Maintenance Plans:

This plans are not available as report formats in any type. We open these plans manually and record the required data one by one in an MS Excel sheet to ensure the integrity.

We used these reports to directly to calculate both calibrated and maintained number of devices in KPI 6 - Total Maintenance Rate, KPI 7 - Calibration Completion Rate and KPI 8 - Uncompleted Preventive Maintenance Rate.

Report dates are always for the year 2008 because MAESTRO is a newly installed system in V.K.V. Amerikan Hastanesi. Data for previous years are not available



TEKNİK TİPE GÖRE EKİPMAN LİSTESİ

TEKNİK TİP	TOPLAM	EKİPMAN TÜRÜ	EKİPMAN ADI	ANA SİSTEM	SİSTEM
Biyomedikal	3486				
		Acil Arabası (16)			
		Açık Yatak (15)			
		Alerji Test Cihazı (1)			
		Operasyon Lambası (36)			
		Anestezi Cihazı (21)			
		Anjiyo/MR/BT Enjektörü (9)			
		Argon Cihazı (1)			
		Lazer Cihazı (Argon) (1)			
		Z_kullanım dışı (26)			
		Z_silinenler (93)			
		Gastroskop (11)			
		Video Recorder (7)			
		Vortex (9)			
		Su Kalorik Stimülatör (1)			
		Wavescan (1)			
		Sedyeler (86)			
		Lazer Cihazı (Yag) (1)			
		Tansiyon Holteri (5)			
		Tartılar (32)			
		T-Dalga Alternans Cihazı (1)			
		Tens Cihazı (28)			
		Termal Cycler (2)			
		Termometre (128)			
		Medikal Amaçlı Soğutucu			
		Dolap (73)			
		Tromboferez Cihazı (2)			
		Tüp Kapatici (Sealing) Cihazi (4)			
		Ultrason (20)			

Figure 5.6 Total Device Counts Report

on the system. Data of 2009 was used where it can be collected but it is available just for the first quarter of 2009.

After transforming the mentioned reports to MS Excel format, they were accessed with the use of C# .NET framework's built-in functions.

5.3 User Interface

The algorithm in C# .NET is written according to the following steps.

- Data selection and loading from MAESTRO reports stored in MS Excel format
- Indicator selection from the user interface
- Monitoring the selected indicator and indicator display (graphical methods in C# .NET using SPC tools)

	Rapordaki cihaz sayısı	Bakım planlarındaki cihaz sayısı	Ocak	Şubat	Mart	Nisan	Mayıs	Haziran	Temmuz	Ağustos	Eylül	Ekim	Kasım	Aralık
Açık Yatak	15	15				15						15		
Ağrı Pompası	20	20	20						20					
Anestezi Cihazı	21	21				21						21		
Anjiyo/MR/BT Enjektörü	9	9			1	5					2			
Bipap Cihazı	7	7					3		1			1	2	
Defibrilatör	18	17		17						17				
Doz Kalibratoru	1	1											1	
Eforlu EKG	3	3												
EKG Cihazı	12	10						10						
Elektrokoter	26	22		20						22				
Embriyo Dondurma Cihazı	1	1				1								1
Etilen Oksit Dedektörü	2	2		2			2			2			2	
Fetal Monitör	7	4												4
Fototerapi Cihazı	6	6				6								
Geiger Müller	1	1			1									
Harici Kalp Pili	12	12				12						12		
Hassas Terazi	9	9				7	1							
Hastabaşı Monitörü	155	151					149							1
IABP	2	2						2						2
İnfüzyon Pompası	200	196				92	101	2						
İnkübatör	17	17									16			
Küvöz	9	9										9		
Mama Pompası	48	48				28	20							
Medikal Amaçlı Soğutucu Dola	73	66		2		62					2			
Mobil Röntgen	2	2							2					
MR Uyumlu Monitör	1	1					1							
Palsoksimetre	53	57											52	
Perfüzör	130	131												
Radyasyon Monitörü	4	4			1					1			1	
Röntgen	4	3							3					
Santrifüj	29	28							28					
Tansiyon Aleti	284	275				101	114		4			20	18	5
Vaporizatör	51	46									46			
Ventilatör	37	37				37						37		
			20	41	3	387	391	14	58	42	66	115	76	13

Figure 5.7 Report of Monthly Calibrations Scheduled

- Indicator evaluation using designed statistical data analysis methods
- Quality improvement opportunities identification

Main front panel is the first panel that the user is faced with when he/she enters the program and it was designed in .NET framework as displayed in Figure 5.9 above. It consists of a list of 8 indicators on the left and their options. Average Response Time, Average Repair Time and Average In-house Repair Time can be monitored weekly or monthly and both per employee and the whole biomedical/clinical engineering department by selecting the preferred option. Total Cost per Repair and Fraction of Failures can be monitored only monthly for each device in the device list, or for each department in the department list shown on the left, providing the user with a good indication of quality performance in the different areas of biomedical/clinical engineering department. Uncompleted Calibration Rate, Uncompleted Preventive Maintenance Rate and

		Ocak				Şubat				Mart				Nisan				Mayıs				Haziran				Temmuz				Ağustos				Eylül				Ekim				Kasım				Aralık			
		1	3	6	Y	1	3	6	Y	1	3	6	Y	1	3	6	Y	1	3	6	Y	1	3	6	Y	1	3	6	Y	1	3	6	Y	1	3	6	Y	1	3	6	Y	1	3	6	Y	1	3	6	Y
Anjiyo Cihazı	4		2	1							1				1								1				2								1				2	1							1		
Bilgisayarlı Tomografi	2						2												2												2										2								
EECP Cihazı	1		1												1																1										1								
Gama Kamera	2		1												1	1											1												1	1								
Hemodiyaliz Cihazı	2	1				1				1				1				1				1				1				1				1				1				1				1			
Hemofiltrasyon Cihazı	2															2																																	
Holmium Lazer Cihazı	1											1																																					
Kalp Akciğer Pompası	2																													2																		
Kemik Densitometresi	1			1																			1																							1		
Mamografi cihazi	1						1								1												1												1								
Mr Cihazı	2						2								1				1								1				1										2								
PET-CT	1						1																																		1								
Skopi	4			1				1											3																							1				2			
Ultrason	9																		7																							6				2			
		8				8				3				9				14				3				6				7				2				7				14				7			

Figure 5.8 Report of Monthly Preventive Maintenances Scheduled

Total Maintenance Rate can only be monitored monthly.

Which month or week will be monitored can be chosen from the calendar on the right side of the user interface. Since the calendar is designed to work with other possible database systems, it does not include only the year 2008 and 2009. It is possible to choose the years, months, weeks and even days from the calendar if the data is available.

The two big white windows in the middle, is the graphic display. On the upper box, the X/p control chart is displayed with its control limits. On the lower box, the tabular cusum chart is displayed with its decision intervals.

The other two boxes on the right were designed to give alarms if the monitor indicator data goes out-of-control. The algorithms to detect the process change were discussed in previous sections. The upper box displays X/p control chart's alarm signals; the lower box displays the tabular cusum chart's alarm signals and comments about possible process changes. We decided to put two alarm boxes because with two boxes, it would be possible to compare the charts and to see the performances of both of them.

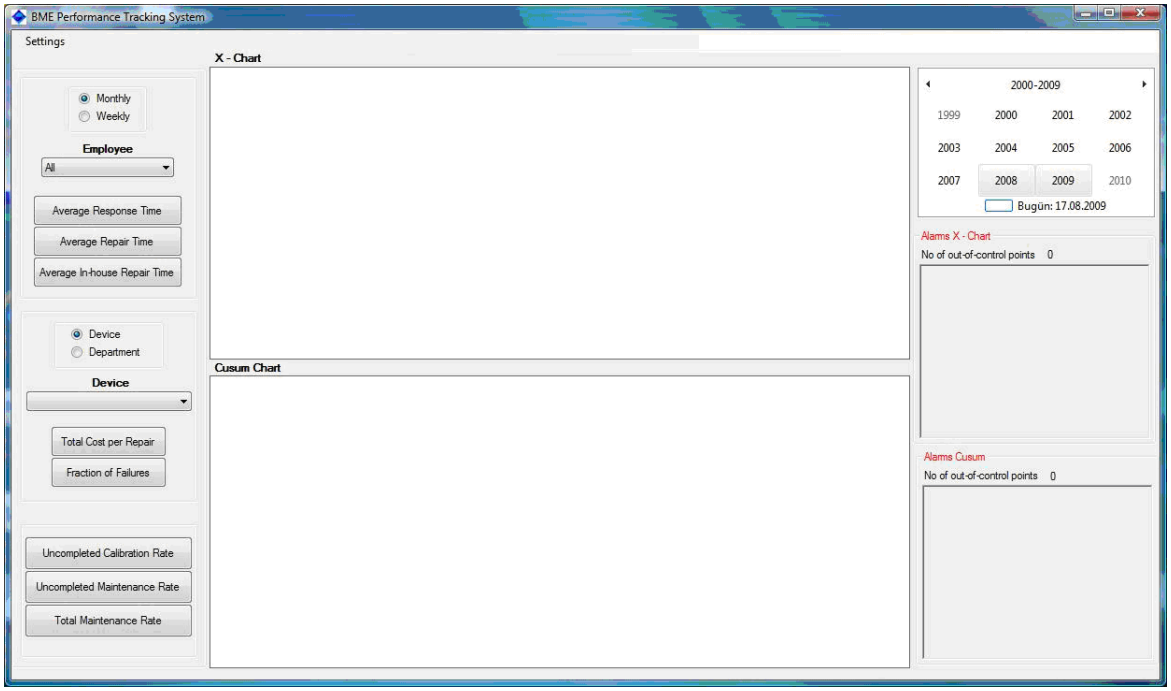


Figure 5.9 The designed user interface

5.3.1 How to use the software?

When you click and open the software, first of all you should load the exported reports in ".xml" format. Click the "settings" button on the upper left corner of the software and choose "Load Files". Then click on the report that you want to load and choose the destination of the report. Although we explained which report is needed for which KPI, we assume that the user of the program could not possibly be qualified enough to remember and also should not waste his/her time on this. So, we recommend the user to load all the reports at once before monitoring the performance.

The unloaded reports appear in red, once you load them they turn into green so you can easily understand which one of them you have already loaded. Then go back to the main front panel.

Now it is time to choose the indicator, which will be monitored. If you choose the indicator Average Response Time or Average Repair Time or Average In-house

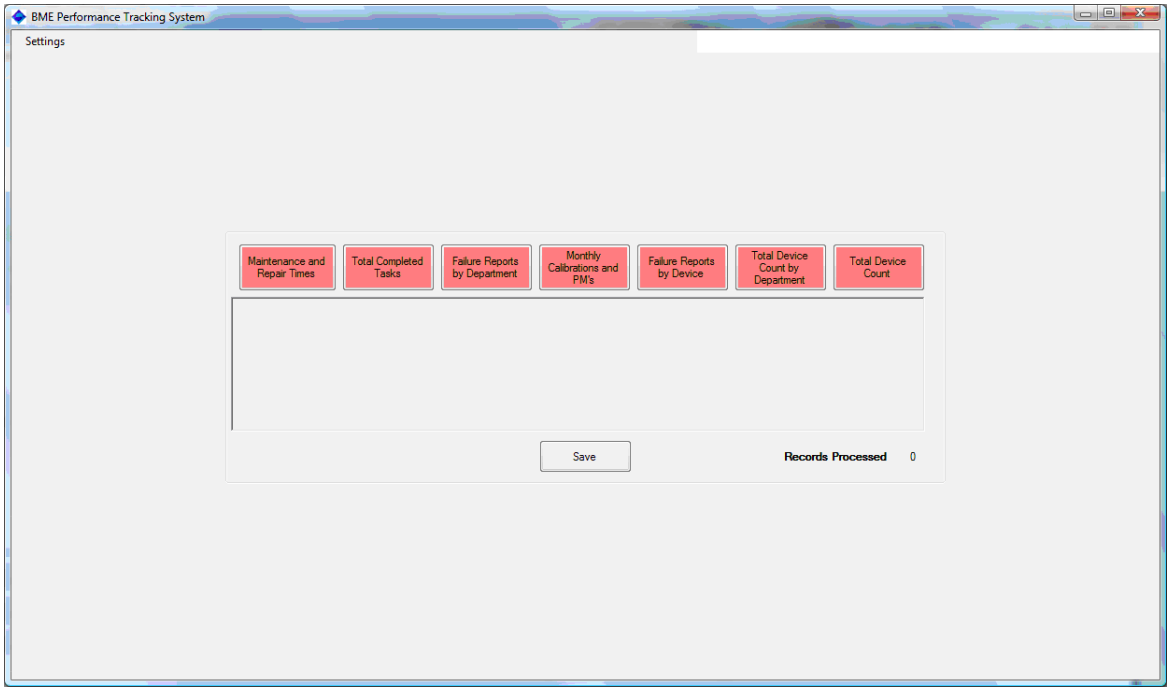


Figure 5.10 Appearance of the user interface during loading of reports

Repair Time, you should also choose the monitoring frequency; monthly or weekly. You can also choose the employee you want to monitor from the dropdown list. If you want to monitor the whole biomedical/clinical engineering department, you do not have to do anything additionally. Then just click the indicator button.

If you choose Fraction of Failures or Total Cost per Repair, you should also decide whether you are going to monitor the indicator departmental based or device based. If you want to monitor a specific device or department, independent from the indicator, you should pick it up from the dropdown list. Then click the indicator button.

If you choose Uncompleted Calibration Rate or Uncompleted Preventive Maintenance Rate or Total Maintenance Rate, you don't have to choose anything, just click the buttons on the left.

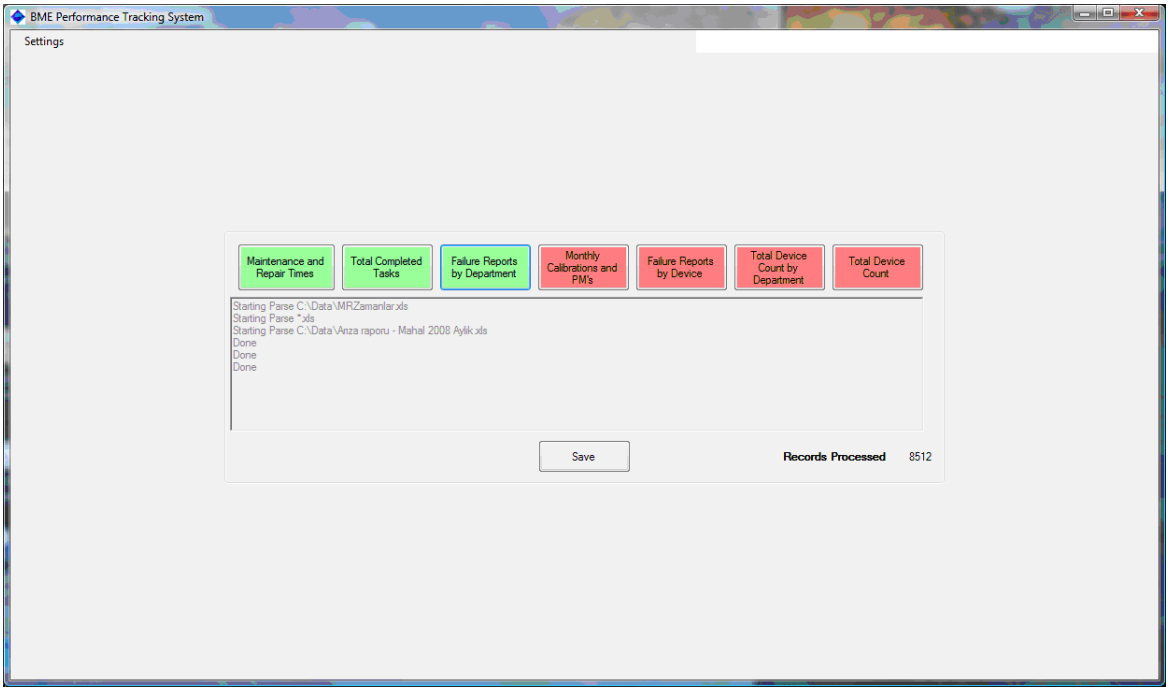


Figure 5.11 Appearance of the user interface during loading of reports

Once you click on any indicator button, you will see two charts in the middle of the main window. The upper chart represents "X/p control chart" and the lower one represents "Cusum chart". It is possible to choose between years, months or weeks from the calendar on the upper right corner of the panel. As we designed our program multi - directional, we do not include only 2008 and 2009 considering only V.K.V. Amerikan Hastanesi. The calendar has a very wide time span. Thus, it is ready to work with several databases in different hospitals.

Two boxes on the right give the alarm signals. Upper box shows the alarm signals of X/p control chart. It displays the "out-of-control" points, counts them and when available, displays the "possible out-of-control points". The box on the bottom displays the cusum chart alarm signals. It counts the "out-of-control" points and displays when the "possible process change" has occurred. By determining the month/week that the possible process change has occurred, this program tries to simulate the judgment and behavior of a human that has expert knowledge and experience in this particular field [3].

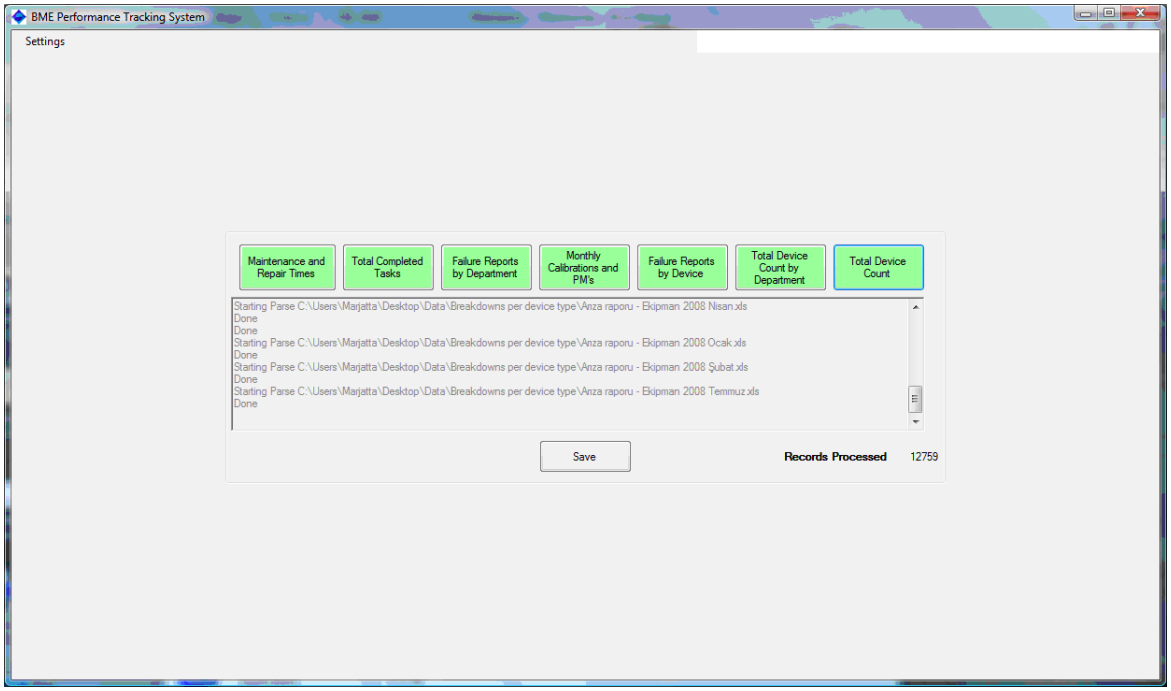


Figure 5.12 Appearance of the user interface during loading of reports

At the end, the user analyzes the graphs and alarm signals, and if needed, he/she builds up a new improvement strategy to eliminate the process changes.

5.3.1.1 A Brief Example. Let's assume that we want to monitor "KPI 5 - Fraction of Failures" for medical imaging department in the hospital. What we must do at the beginning is to load the required reports. We click on the "Settings" part and select "Load Files". All of them are red because we have not load any of them yet.

As we don't know which report is required for KPI 5, we choose to load all the reports. By the time the reports are loaded, the boxes turn green. We click on the "Save" button and we return to the main panel.

We check "Department" section and choose "medical imaging (tıbbi görüntüleme)" from the dropdown list. Since data for this indicator can be reported once a year, we only have data for 2008. Thus the calendar on the right shows the year 2008.

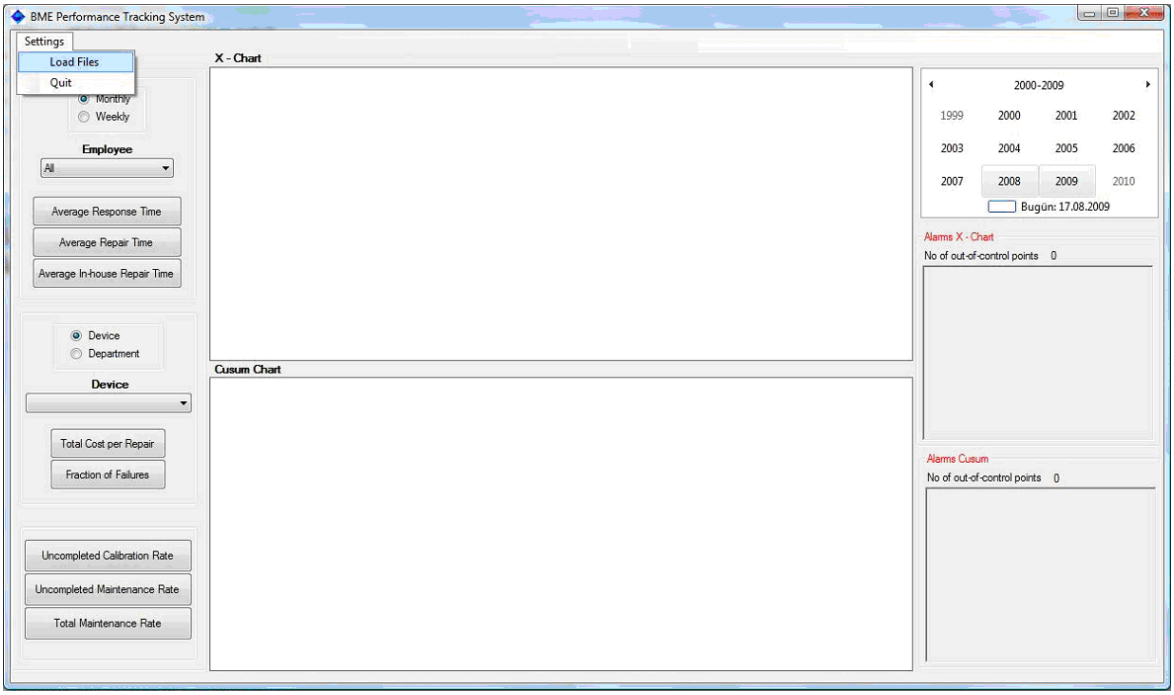


Figure 5.13 How to load needed files by using the user interface

We click the indicator button "Fraction of Failures". As soon as we click the button, the charts and alarm signals are displayed. The upper graph displays X control chart and the little box on the right show out-of-control points.

By looking at the X control chart, we can say that the process is in control because there are no out-of-control points that lie outside the control limits. To confirm our findings, we look at the alarm box and we see that the box does not alarm. This may not mean anything to the user and the user can need a more specific chart interpretation. That is the reason why we have also implemented the cusum chart to this software.

If we move on to the lower chart, the cusum chart, we see a brief example of a tabular cusum chart with decision intervals. By looking carefully at the chart, we see that there are also no out-of-control points like in the X chart. To confirm our findings we look at the little alarm box on the right corner. The box does not alarm either. Now that the user is sure that there hasn't been a possible process change and the

whole picture becomes clearer for her/him.

As seen in the example, the designed software provides a comprehensive statistical process control system which accomplishes all the major goals as outlined at the beginning of this chapter.

6. RESULTS

In this part of the study, we are going to analyze examples of charts generated by our designed expert system for each indicator and make conclusions.

The results obtained from statistical analysis performed in .NET Framework were verified with MS Excel. Control charts were implemented with MS Excel and the results were compared with the ones displayed in designed front panel in .NET Framework. The comparison was successful and data was verified.

KPI 1 - Average Response Time

We chose to monitor Average Response Time monthly, for the whole biomedical engineering department and for year 2008. We clicked the button and the charts have appeared in the graphical display.

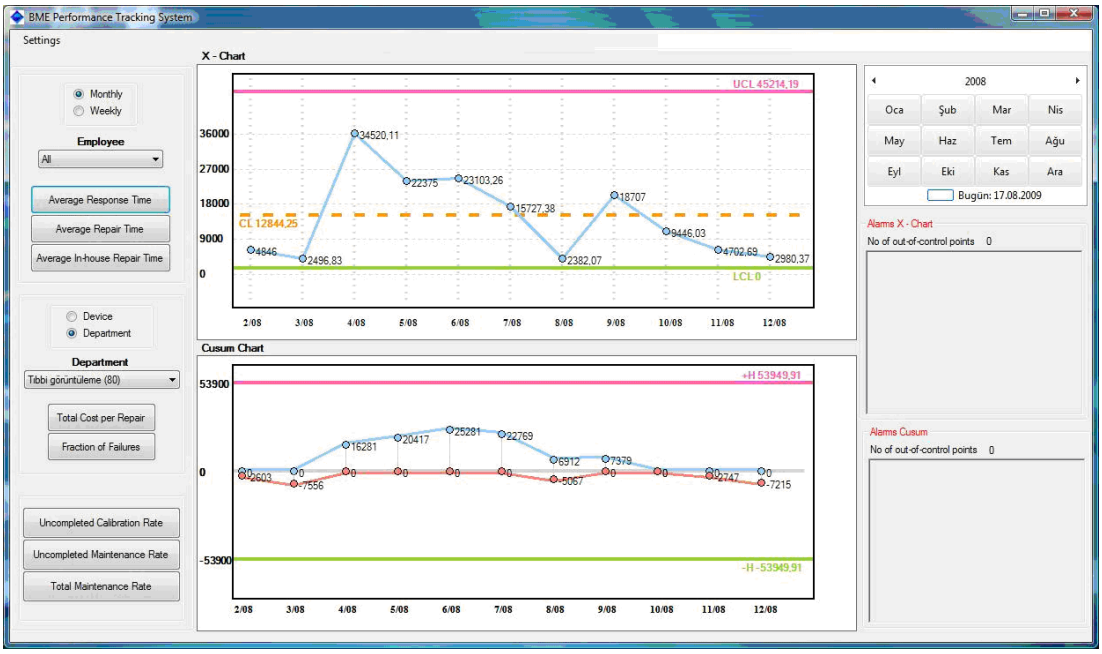


Figure 6.1 Appearance of the user interface for KPI -Average Response Time

Looking at the graphics, we see that the chosen indicator was in control for 2008 according to both X-chart and cusum chart.

KPI 2 - Average Repair Time

We chose to monitor Average Repair Time weekly, for the employee "Hamit Gül" from the biomedical engineering department and for year 2008. We clicked the button and the charts have appeared in the graphical display.

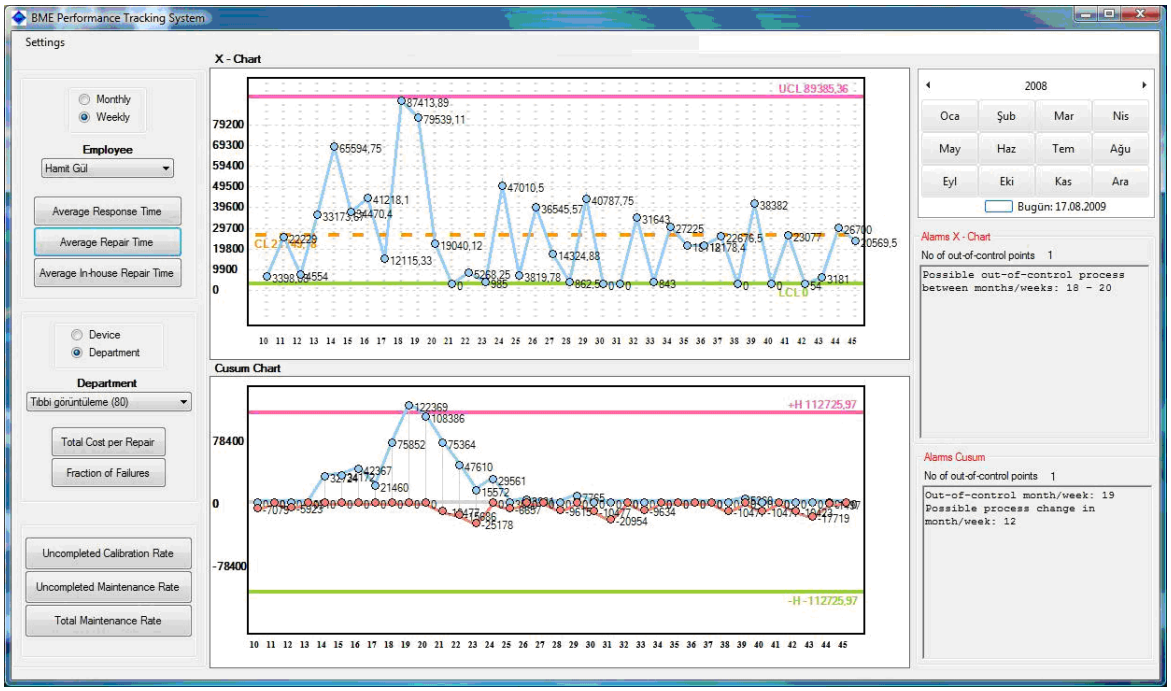


Figure 6.2 Appearance of the user interface for KPI -Average Repair Time

Looking at the X-chart, we see that the chosen indicator was out-of-control possibly between the 18^{th} and 20^{th} weeks in 2008. Since there is no point above the upper control limit, the X-chart can not "definitely" determine if there was a "definite" out-of-control point, but with the rules described in the previous parts, it can make a prediction that there is one between displayed weeks. Unlike the X-chart, cusum chart has detected a "definite" out of control point at 19^{th} week. Notice that it was the week the X-chart predicts. With its strong features, cusum chart also made a prediction

that the possible process change had happened in 12^{th} week. Thus, our prediction of Cusum's performance was confirmed.

Knowing when the possible process change has occurred is better for the user rather than knowing the month/week of the out-of-control point. It gives the user the chance to investigate deeply that period because it is that "change" which causes the process go out of control.

KPI 3 - Average In-house Repair Time

We chose to monitor Average In-house Repair Time weekly, for the whole biomedical engineering department and if available for years 2008 and 2009. We clicked the button and the charts have appeared in the graphical display.

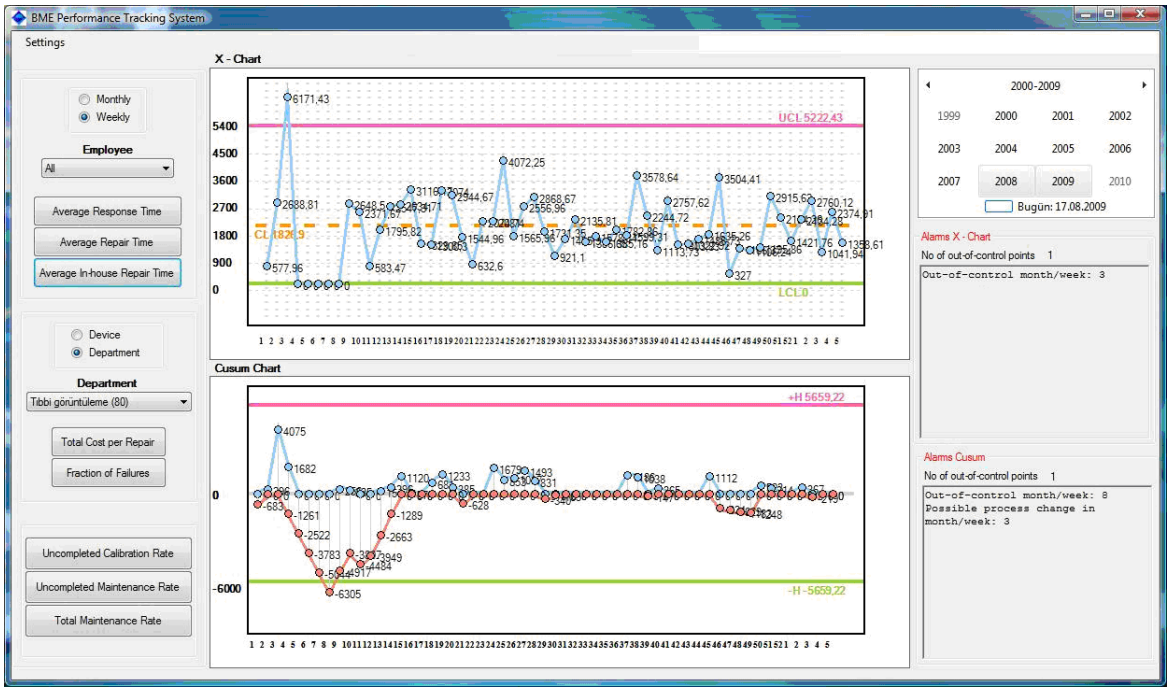


Figure 6.3 Appearance of the user interface for KPI -Average In-house Repair Time

Since data is only available for the first two months of 2009, the x-axis of the charts includes the first five weeks. Looking at "Alarm Boxes", we see that both

X-chart and cusum chart have detected only one out-of-control point. Notice that although cusum chart detected an out-of-control point at 8^{th} week, it predicts the possible process change has occurred at 3^{rd} week which is consistent with the X-chart.

KPI 4 - Total Cost per Repair

We chose to monitor Total Cost per Repair for "device", for infusion pumps. Since the data for this indicator is only available annually, we choose 2008 from the calendar. We clicked the button and the charts have appeared in the graphical display.

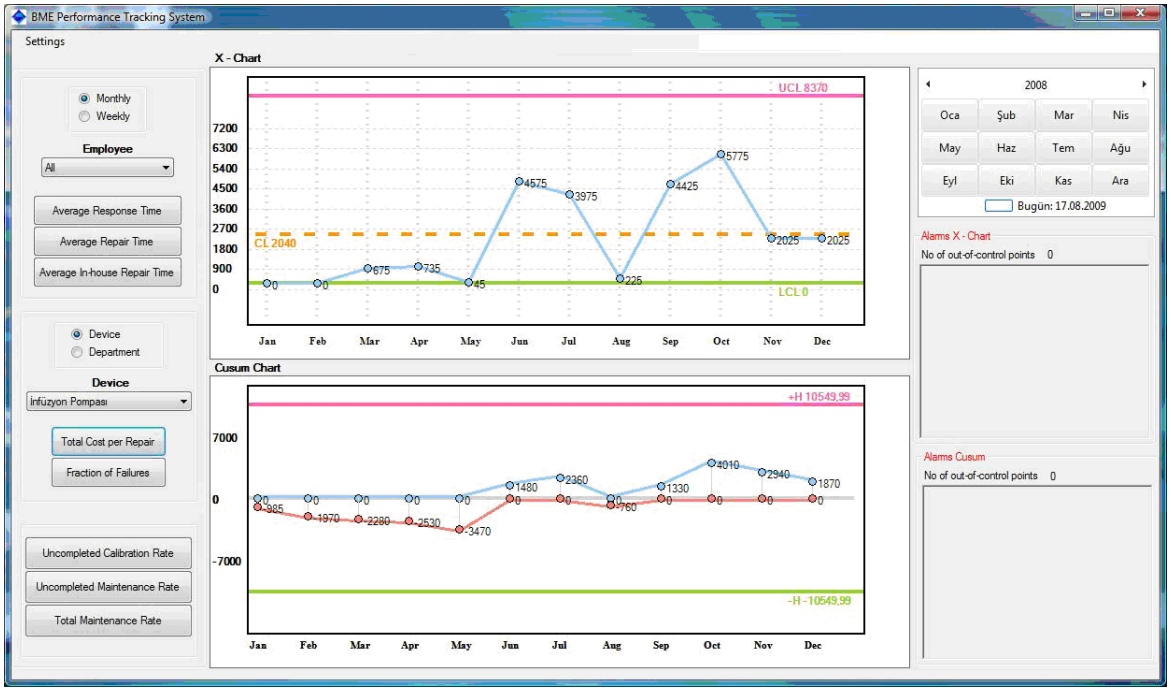


Figure 6.4 Appearance of the user interface for KPI - Total Cost per Repair

Looking at the graphics, we see that the chosen indicator was in control for 2008 according to both X-chart and cusum chart.

KPI 5 - Fraction of Failures

We chose to monitor Fraction of failures for "gastroenterology" department. Since the data for this indicator is only available annually, we choose 2008 from the calendar. We clicked the button and the charts have appeared in the graphical display.

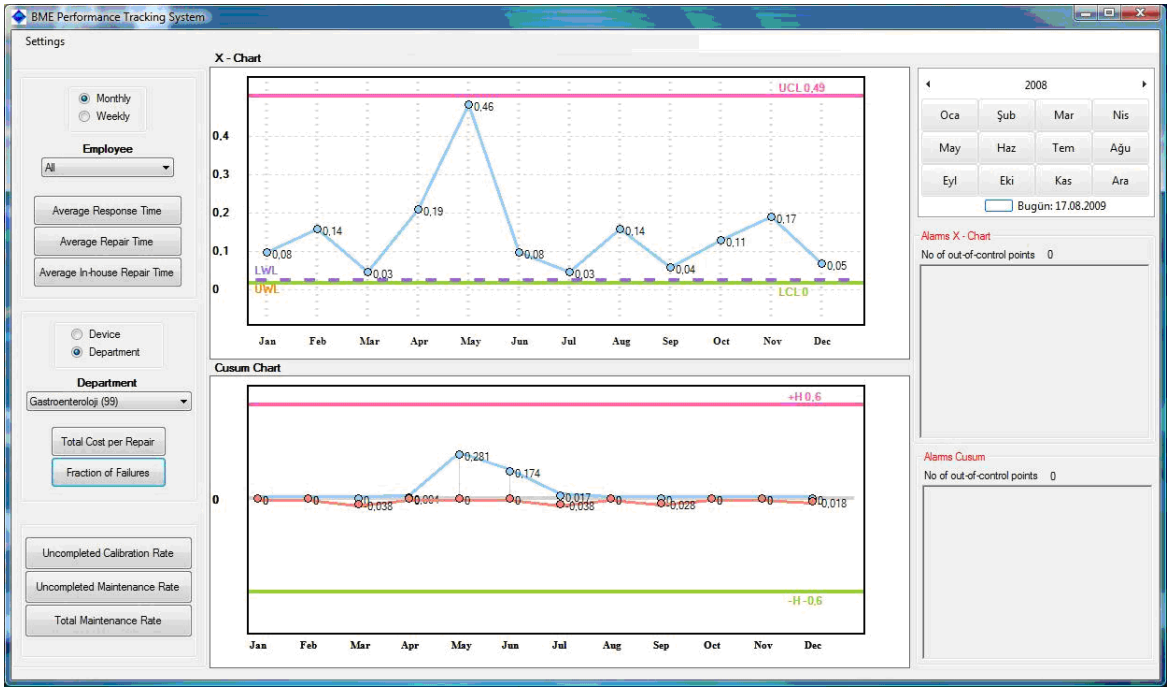


Figure 6.5 Appearance of the user interface for KPI - Fraction of Failures

Looking at the graphics, we see that the chosen indicator was in control for 2008 according to both X-chart and cusum chart.

KPI 6 - Total Maintenance Rate

We chose to monitor Total Maintenance Rate. Since the data for this indicator is only available for 2008 for now, we choose it from the calendar. We clicked the button and the charts have appeared in the graphical display.

Looking at the X-chart, we see that the chosen indicator was possibly out-of-

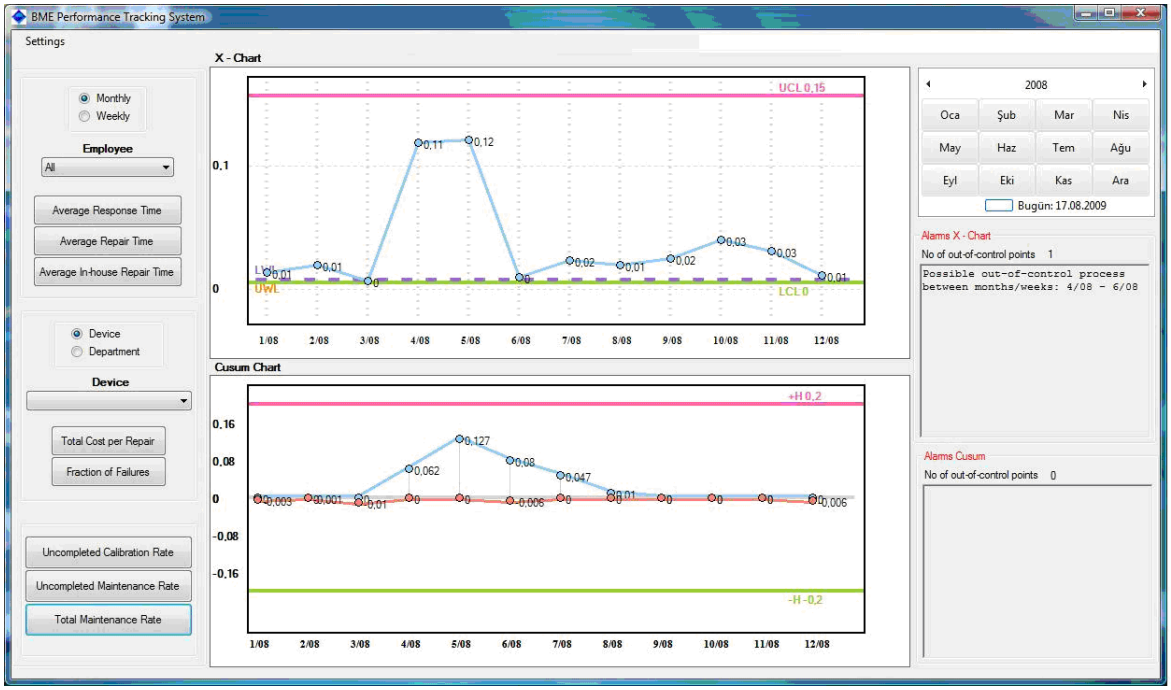


Figure 6.6 Appearance of the user interface for KPI - Total Maintenance Rate

control between April and June in 2008. With this result, it is not possible to make a decision for the user. In contrast to X-chart, cusum chart has detected "0" out-of-control points. This shows that the X-chart gives a false alarm, with which our prediction of Cusum's better performance was confirmed.

KPI 7 - Uncompleted Calibration Rate

We chose to monitor Uncompleted Calibration Rate. Since the data for this indicator is only available for 2008 for now, we choose it from the calendar. We clicked the button and the charts have appeared in the graphical display.

Looking at both X-chart and cusum chart, we see the process was in control in 2008 and on top of it, these graphs implement that all the calibrations planned were completed.

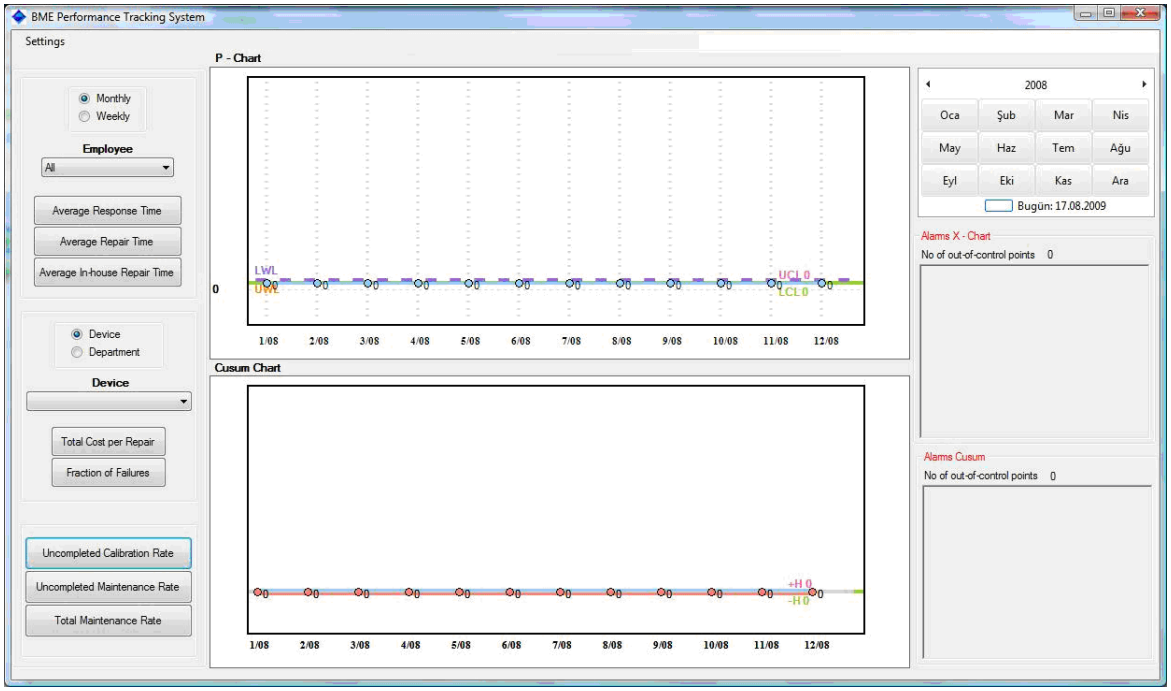


Figure 6.7 Appearance of the user interface for KPI - Uncompleted Calibration Rate

KPI 8 - Uncompleted Preventive Maintenance Rate

We chose to monitor Uncompleted Preventive Maintenance Rate. Since the data for this indicator is only available for 2008 for now, we choose it from the calendar. We clicked the button and the charts have appeared in the graphical display.

Looking at both X-chart and cusum chart, we see the process was in control in 2008 and on top of it, these graphs implement that all the preventive maintenances planned were completed.

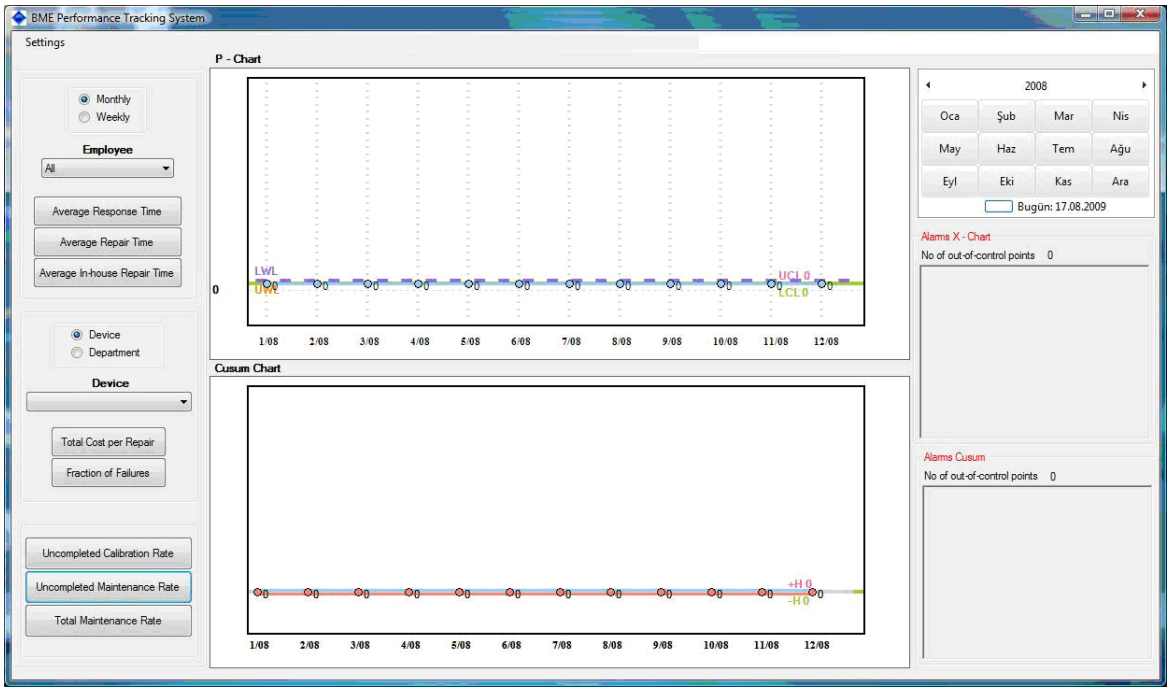


Figure 6.8 Appearance of the user interface for KPI - Uncompleted Preventive Maintenance Rate

7. DISCUSSION

In this chapter, simply the advantages and limitations of the designed system will be discussed. Improving control charts' sensitivity, improving cusum charts' responsiveness and ways to improve the design and the performance of the developed system are the other topics.

7.1 Discussion of Sensitizing Rules for Control Charts

As maybe gathered from earlier sections, there are several rules that may be applied simultaneously to a control chart to determine whether the process is out of control. The basic criterion is one or more points outside of the control limits. The supplementary criteria are sometimes used to increase the "sensitivity" of the control charts to a small process shift so that we may respond more quickly to the assignable cause. Some of the sensitizing rules that are widely used in practice are shown in the following table 7.1.

For a good discussion of these rules, see Nelson (1984) [50]. Frequently, we will inspect the control chart and conclude that the process is out of control if any one or more of the criteria in table 7.1 are met.

When several of these sensitizing rules are applied simultaneously, we often use a "graduated response" to out-of-control signals. For example, if a point exceeded a control limit, we would immediately begin to search for the assignable cause, but if one or two consecutive points exceeded only the two-sigma warning limit, we might increase the frequency of sampling from every hour - say, to every 10 minutes. This "adaptive sampling" response might not be as severe as a complete search for an assignable cause, but if the process were really out of control, it would give us high probability of detecting this situation more quickly than we would by maintaining the longer sampling interval. Since increasing the frequency of "sampling" is not possible for our indicators

Table 7.1
Some Sensitizing Rules for Shewhart Control Charts

Some Sensitizing Rules for Shewhart Control Charts		
Standard Action Signal:	1. One or more points outside of the control limits. 2. sigma warning limits but still inside the control limits. 3. Four of five consecutive points beyond the one-sigma limits. 4. A run of eight consecutive points on one side of the center line. 5. decreasing. 6. Fifteen points in a row in zone C (both above and below the center line). 7. down. 8. Eight points in a row on both sides of the center line with none in zone C. 9. An unusual or nonrandom pattern in the data. 10. One or more points near a warning or control limits.	Western Electric Rules

Table 7.2
The Control Chart

in hospital environments, we can not use "adaptive sampling" technique in our study.

Champ and Woodall (1987) [36] investigated the average run length performance for the Shewhart control chart with various sensitizing rules. They found that the use of these rules does improve the ability of the control chart to detect smaller shifts, but the in-control average run length can be substantially degraded. For example, assuming independent process data and using a Shewhart control chart with the Western Electric rules results in an in-control ARL of 91,25, in contrast to 370 for the Shewhart control chart alone.

Some of the individual Western Electric rules are particularly troublesome. An illustration is the rule of several (usually seven or eight) consecutive points which either increase or decrease. This rule is very ineffective in detecting a trend, the situation for which it was designed. It does, however, greatly increase the false-alarm rate. See

Davis and Woodall (1988) [51] for more details [28].

7.2 Improving Cusum Responsiveness for Large Shifts

We have observed that the cusum control chart is very effective in detecting small shifts. However, the cusum control chart is not as effective as Shewhart chart in detecting large shifts. An approach to improving the ability of cusum control chart to detect large process shifts is to use a "combined cusum-Shewhart procedure" for on-line control. Adding the Shewhart control is a very simple modification of the cumulative sum control procedure. The Shewhart control limits should be located approximately 3,5 standard deviations from the center line or target value μ_0. An out-of-control signal on either (or both) charts constitutes an action signal. Lucas (1982) [52] gives a good discussion of this technique. Column (a) of table 7.2 presents the ARLs of the basic cusum with $k = \frac{1}{2}$ and $h = 5$. Column (b) of the table 7.2 presents the ARLs of the cusum with Shewhart limits added to the individual measurements. As suggested above, the shewhart limits are at $3{,}5\sigma$. Note from examining these ARL values that the addition of the Shewhart limits has improved the ability of the procedure to detect larger shifts and has only slightly decreased the in-control ARL_0. We conclude that a combined cusum-Shewhart procedure is an effective way to improve cusum responsiveness to large shifts and in a way we've demonstrated this approach in this study with 3σ control limits.

7.3 The Fast Initial Response or Headstart Feature

This procedure was devised by Lucas and Crosier (1982) [53] to improve the sensitivity of a cusum at process start up. Increased sensitivity at process start up would be desirable if the corrective action did not reset the mean to the target value. The "fast initial response (FIR) or headstart" essentially just sets the starting values C_0^+ and C_0^- equal to some nonzero value, typically H/2. This is called a 50% headstart.

Table 7.3
ARL Values for Some Modifications of the Basic Cusum with $k = 1/2$ and h=5

Shift in Mean (multiple of σ)	**(a)** Basic Cusum	**(b)** Cusum-Shewhart (Shewhart limits at $3,5\sigma$)	**(c)** Cusum with FIR	**(d)** FIR CusumShewhart (Shewhart limits at $3,5\sigma$)
0	465	391	430	360
0,25	139	130,9	122	113,9
0,5	38	37,2	28,7	28,1
0,75	17	16,8	11,2	11,2
1	10,4	10,2	6,35	6,32
1,5	5,75	5,58	3,37	3,37
2	4,01	3,77	2,36	2,36
2,5	3,11	2,77	1,86	1,86
3	2,57	2,1	1,54	1,54
4	2,01	1,34	1,16	1,16

If the process starts in control at the target value, the cusums will quickly drop to zero and and the headstart will have little effect on the performance of the cusum procedure. However, if the process starts at some level different from the target value, the headstart will allow the cusum to detect it more quickly, resulting in shorter out-of-control ARL values.

Column (c) of the table 7.2 presents the ARL performance of the basic cusum with the headstart or FIR feature. The ARLs were calculated using a 50% headstart. Note that the ARL values for the FIR cusum are valid for the case when the process is out of control at the time the cusums are reset. When the process is in control, the headstart value quickly drops to zero. Thus, if the process is in control when the cusum is reset but shifts out of control later, the more appropriate ARL for such a case should be read from column (a) - that is, the cusum without the FIR feature.

As the cusum charts that give alarms like "possible process change before Jan" in our software denotes the shift has occurred prior to the onset of monitoring, we can

use the headstart feature which will signal faster on average.

Thus far we've talked about statistical calculation improvements and how we can implement them to our study. From now on we will be talking about the limitations we've come across and better ways of design for an improved system.

7.4 Limitations of the Maintenance, Repair, Equipment and Stock Management Software (MAESTRO)

The most challenging part of this study is certainly working with MAESTRO, V.K.V. Amerikan Hastanesi biomedical/clinical engineering department's maintenance, repair, equipment and stock management software program. There are several disparities that we tried to accommodate with.

The very first limitation for us is the "data quality". The data quality is outside the scope of our aim here, and we did not try to monitor the chosen hospital's performance, but it would have been better if there's more statistically significant and "qualified" data.

Low data quality for biomedical/clinical engineering department in the chosen hospital is a result of misusing the software (MAESTRO). Misusing is totally an user-based problem. Although the users of the software should enter the data properly, they leave blanks in required fields of the forms. This can be solved by the software itself. The required fields of the forms could be defined. If the user skips one of these fields, the software could warn the user. For example, a blinking pop-up box could appear and notify the user and the software will not close the order/form until the blank fields are completed. Lack of this kind of a control system is the biggest disadvantage of MAESTRO.

To avoid low data quality, it is not always enough to constitute a control system. The users of the software should take training before using it. Although the software may help the users not to do any mistakes, the users should also be very careful. They should enter the data "completely" for the required fields and they should enter them "on time". For example, if they open a repair order, and not close it by the time the repair ends, the software will close it automatically at the end of the year. In this way, a repair that lasts for, let's say, 4 days, will appear on the software as if it lasts for, let's say, 4 months. Thus, the data quality and significance will decrease and the performances will appear lower than the real values.

Let's take a closer look at the "costs" section of MAESTRO. MAESTRO has entries for three kinds of costs; labor costs, material (spare parts) costs and service costs. It calculates the total cost by summing up these three costs. The users of MAESTRO did not enter the values for spare part costs and service costs. Hence, we could only monitor the labor costs. As other two types of costs were incomplete, the total cost did not reflect the real value, because it is equal to the labor costs. In spite of this incomplete data, we designed our software as there were data for other types of costs. But it would have been better if we could also monitor the spare part and service costs and maybe we could have added an extra KPI to analyze them.

In our study, we tried to eliminate this unqualified and insignificant data together with the head of biomedical/clinical engineering department of the hospital. If the data could have been more significant, it would have been easier for us to analyze.

The second limitation for us is the deficiencies on the forms of MAESTRO. We simply would be very glad if there are more information available. We adapted our KPI according to the available data in MAESTRO. If MAESTRO has been more flexible, we could have defined more precise KPI and analyze them more ambidextrously.

Data entry must be standard for some forms. For example, for a work order the user should always enter the "device/equipment" that causes trouble, location of the troubled device/equipment (departmental information) and the exact times. This work

order includes all failures, calibrations, preventive maintenances etc. In MAESTRO, in calibration and maintenance plans, there is no departmental or employee based data available, so we can only monitor them hospital-wide. It would have been very nice to monitor the Calibration and Maintenance Completion Rates departmentally, or employee based.

Another deficiency case is about work orders. When we chose a repair or a calibration order, we had difficulty to understand if it is an in-house repair/calibration or not. There must be information on the work orders defining if the order is under the responsibility of the biomedical engineering department of the hospital or a contracted firm. It can be solved by just putting a check-box on the forms. The user can put a check in the box if it is an in-house work order. Otherwise, it is not possible to differentiate the work orders and because of the firm's slipperiness, the departmental performance can appear lower.

The third limitation is the lack of the reports in MAESTRO. It is true that there are several practical reports, but it was not understandable not to have calibration and maintenance plans in a report format. We had to create the plans manually ourselves to calculate the Calibration and Maintenance Completion Rates. If we did not create these plans and import them to MS Excel, it would not be possible for us to calculate KPI 6 - Total Maintenance Completion Rate, KPI 7 - Uncompleted Calibration Rate and KPI 8 - Uncompleted Preventive Maintenance Rates just from the closed calibration and maintenance work orders. Setting us aside, a biomedical/clinical engineering department's maintenance, repair, equipment and stock management software program should have been keeping these completion rates by itself in a report format and displays the user if there is a change in the processes.

The fourth limitation is the frequency of the reports available. Since the software has all required date and time information from "total completed tasks", it is not possible to export reports on a regular weekly or monthly basis. While some reports are available at any time without any time limitation, some reports are available only annually. For example if you want to see the number and costs of failures depart-

mentally, you should wait until 31 December of that year. This complexity ruins the integrity of our designed software program and causes some updating problems that will be explained in the following paragraphs. It would have been better if all the reports can be accessible at anytime for any chosen time-span.

The last limitation arises from not using MAESTRO's own database. We use data of the MAESTRO by arranging them in report formats and exporting them to MS Excel. Using reports in MS Excel and loading them manually before starting to analyze indicators in our program causes some updating problems. As mentioned earlier, we assume that the user of the program could not possibly be qualified enough to remember which report is required for which indicator and the frequency which the reports should be generated by using MAESTRO. To eliminate that kind of user-based problems, we recommend our users to load all the reports independent from the indicator they want to monitor and load them on a regular basis, let's say monthly.

This, however, disintegrates the system and decreases the performance of the software but it is our choice since we do not find it ethical to reach confidential information of both the hospital and the software company that creates MAESTRO. While not using MAESTRO's own database has the disadvantage of lower performance and a bit of disintegrity, it is advantageous in a way that it can be used not only in the hospitals, which uses MAESTRO as maintenance, repair, equipment and stock management software, but also in the other hospitals with different softwares. It is enough to have the feature of creating reports in MS Excel format for the other software packages to work with our developed program.

We, of course, have preferred to write our own maintenance, repair, equipment and stock management software. Then, we did not have to define our KPI according to the data available and accessible. We would create the data we need and all these statistical process control methods and graphical displays would be included in the designed system. There would not be any need for extra software packages/patches like ours. As, there are several examples of this type of stock management programs in the market and it is much costly and unnecessary to develop an extra one, it will be

wise to write a small SPC software package like we did and to manipulate it with the other stock management softwares available in the market. Use of Microsoft's .NET Framework for developing the software, gives the required flexibility to be manipulated with any program that operates with MS Windows.

7.5 Mathematical limitations

We've also dealt with some limitations in the statistical calculations of the study. There are times when the "p control chart" can not function. For example, in KPI 7 - Uncompleted Calibration Rate, if the number of performed calibrations is greater than number of planned calibrations, number of uncompleted calibrations become smaller than zero. To fix this, we've neglected the additional calibrations and maintenances performed. Since we are dealing with "uncompleted rates", we only care if the planned jobs are completed. Thus, the number of uncompleted calibrations can never be smaller than zero.

7.6 Better design ideas and Future Work

We are very confident with our design but we wanted to explain why we did not include some extra features. We could have configured our software to take user entry for the control limits of the X control chart or for the target values of the cusum chart. However, we kept our program as simple as possible, thinking that the users of the software in the hospital will not be qualified or authorized enough for this decision. For next step, an executable file can be created for the SPC System and can be installed at V.K.V. Amerikan Hastanesi, Istanbul. Thus, feedback for the relevance and usefulness of the indicators measured and analyzed, the overall design and layout, use of graphical tools and their design and accessibility of the user interface will be provided and this feedback will constitute the part of future software development for this control system.

8. CONCLUSION

The primary objective of this study was to design and develop a control system especially for biomedical engineering departments in hospital environments to monitor, control and improve implementation of different quality and performance indicators.

With the designed control system, the biomedical engineering departments will be capable of constantly monitoring the predefined indicators and make appropriate changes where necessary in order to avoid any potential losses. This is especially applicable to the medical equipment breakdown and cost per service call indicators. The designed system will work closely with the medical equipment database, which can export MS Excel formatted reports, for real-time data input. This makes it capable of being extended for the implementation of other indicators from different databases.

The completed design of our software in .NET Framework established an extensive statistical process control system, achieving all other major goals; detection, location and assignment of causes of special, uncontrolled variation within a pre-specified indicator process. Use of such an expert system will enable the user to be notified of any potential problems, just in time to implement various techniques for their improvement. This ideally constitutes an on-line control system, which can be used effectively by the biomedical engineering as well as other departments to continuously improve quality in healthcare and any other disciplines.

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