DESIGN OF A MEDICAL EQUIPMENT MANAGEMENT SOFTWARE

by

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DESIGN OF A MEDICAL EQUIPMENT MANAGEMENT SOFTWARE

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ABSTRACT

DESIGN OF A MEDICAL EQUIPMENT MANAGEMENT SOFTWARE

In this thesis, a medical equipment management system is developed for online access to the medical assets in a healthcare facility to control, plan, schedule and manage the medical equipment preventive maintenance and calibration processes.

The system consists of hospital equipment inventory management, personnel imformation in charge of medical equipment, equipment failure and maintenance record registration, preventive maintenance and calibration management, analysis and graphical representations.

A password protected, user friendly web interface is provided for easy, universal and secure access to the system.

The system is built over a workstation and controlled from an online web site. Microsoft SQL database and .NET platform is used for the preparation of the system. All codes of the system were written with C# programming language.

Keywords: Medical Equipment Management, Preventive Maintenance.

ÖZET
TIBBİ CİHAZ YÖNETİM YAZILIMI TASARIMI

Bu tez bir sağlık kurumundaki tıbbi cihazların kontrolü, planlaması, tıbbi cihaz koruyucu bakım ve kalibrasyon işlemlerinin yönetimi ve takvimlendirilmesi için geliştirilmiş, çevrim içi çalışan bir tıbbi cihaz yönetimi sistemidir.

Sistem hastane cihaz envanter yönetimi, tıbbi cihazlardan sorumlu personelin tanımlanması, tıbbi cihaz arıza ve bakım kayıtları, koruyucu bakım ve kalibrasyon yönetimi, tıbbi cihazlar ile ilgili analizler ve grafiksel gösterimlerden oluşmaktadır.

Şifre korumalı, kullanıcı dostu bir ağ arayüzü ile sisteme kolay, evrensel ve güvenilir erişim sağlanmıştır.

Sistem bir iş istasyonu üzerinde çalışmakta ve bir ağ sayfası üzerinden çevrimiçi olarak kontrol edilmektedir. Sistem hazırlanmasında Microsoft SQL veritabanı ve .NET platformu kullanılmıştır. Sistemin tüm kodları C# programlama dili ile yazılmıştır.

Anahtar Kelimeler: Tıbbi Cihaz Yönetimi, Koruyucu Bakım

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LIST OF ABBREVIATIONS

AEMR	Adjusted Equipment Management Rating
EM	Equipment Management
EMR	Equipment Management Rating
ECRI	Emergency Care Research Institute
FDA	Food and Drug Administration
GRS	Gradient Risk Sampling
HIMMS	Healthcare Information and Management Systems Society
HIS	Hospital Information System
ICU	Intensive Care Unit
IT	Information Technologies
JCAHO	Joint Commission on the Accreditation of Healthcare Organizations
LAN	Local Area Network
MDA	Medical Devices Agency
ME	Medical Equipment
MEMS	Medical Equipment Management System
PM	Preventive maintenance
RCF	Repair Cost Factor
SPI	Safety and Performance Inspection
SQL	Structured Query Language
UMDNS	Universal Medical Device Nomenclature System

1. INTRODUCTION

The use of computers, computerized equipment and software applications have increased enormously in the healthcare industry. The most probable reason of this increase is that, computerized systems bring easiness, robustness and reliability to healthcare processes. Information systems have been started to be used in healthcare due to increasing cost of high quality care in healthcare services and also competition in healthcare organizations.

When a person compares the past and the present status of information technologies applied to healthcare sector, there is a huge progress. There is a big shift from paper-based to computer-based processing and storage of data. Healthcare centers allocate large budgets to hire programmers to develop their own software or to buy ready-made ones.

As defined by Degoulet and Fieschi [1], a computer system can be designed to ease the management of all the hospital's medical and administrative information and to improve the quality of healthcare.

It can either be used for electronic medical records for the patients or can be used for only medical equipment management. However these implementations are generally very costly due to investments on software and hardware, long implementation duration, complex hospital processes and possible difficulties during implementation.

This thesis is a small application that is mostly interested in medical equipment which are the key elements in monitoring, diagnosis and treatment of patients. The designed system is used to manage the medical equipment maintenance program, to optimize the planned maintenance operations, to localize the medical equipment in the hospital and to keep an updated database of the equipment.

The system is capable of scheduling maintenance program automatically and present the calibration and maintenance due dates of the equipment. It also gives graphical

representation of some important parameters for the clinical engineers such as downtimes and uptimes of the equipment, repair costs, failure rates, failure reasons and replacement planning.

Designed system increases the traceability of the equipment; optimizes the working schedule of the clinical engineering personnel, and increases the quality of processes of medical equipment. It also provides communication between technical and medical departments and increase the safety and regulatory issues. System is working online and can be accessible via Local Area Network (LAN). Therefore departments can report equipment malfunctions through LAN. This accelerates the reporting process.

2. THEORY

2.1 Information Technology in Healthcare

Information Technology (IT) is becoming more prevalent in healthcare. It aims to improve the quality and safety of patient care by cooperating healthcare workers and ease their responsibilities. Many of the medical procedures are planned and prepared, patient appointments and physicians visits are scheduled, patient information are kept, laboratory test and results are transported, reports are generated and transmitted, medical equipment management is provided, payments and insurance processes are controlled by hospital information systems [2].

Since these processes are very complex, there are some software implementation problems in healthcare information systems. In spite of these problems, computerized systems meet the needs of the healthcare organizations and decrease their workflow and increase the quality of the service. Also there is a cost factor of IT systems. Total cost of all kind of healthcare processes done by information systems is lower than systems based on manual work.

Like all other application types of information systems, healthcare systems are designed according to a simple three step rule: “design- evaluation- implementation rule [2].

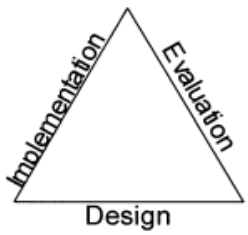


Figure 2.1 Design-evaluation-implementation triangle [2].

All arms of the triangle should interact with each other at every step of the project. In healthcare projects, there is often a change in the system. Therefore the programmers should follow this triangle rule, pay attention to the end users needs and relate every phase with other two.

End-users' needs are very important when designing the system. Programmers should contact with end-users in all steps of the project. This is an important component of the implementation process. The programmer and the end-user interaction make the system more reliable. It also speeds up the process.

Information technology helps to reduce hospital errors. A consumer survey sponsored by Siemens Medical Solutions indicates that 43 percent of Americans believe overworked staff is the leading cause of medical errors in hospitals. The survey also reveals that 16 percent of consumers report medical errors as their biggest concern in healthcare, over cost or quality of care [3].

According to a report released by the Institute of Medicine almost 100,000 patients die annually due to other medical errors. Advancements in IT for the medical environment can help hospitals alleviate these concerns, enabling clinical staff to concentrate on providing the best care for their patients, not administrative data.

2.2 Problems and Challenges of Health Information Systems

It is certain that the use of information technology has innumerable opportunities for the physicians, health care workers and end-users. It reduces the clinical errors, reduces the time consumed when clinical or diagnostic information transferred between clinical departments, supports real time availability of patient information, and improves the total quality of patient care [4].

It is claimed that past experience suggests that efforts to introduce clinical information systems into practice settings will result in failures and unanticipated

consequences if their technical aspects are emphasized and their social and organizational factors are overlooked [5].

There are a number of difficulties of using information technology in health care. The most important hazard is the cost of this kind of projects. Healthcare Information and Management Systems Society (HIMMS) is preparing annual trends in healthcare information technology. Last year, sixty-seven senior-level physician or nursing executives throughout the United States is completed the self-administered Web-based questionnaire. According to this questionnaire, respondents are asked to identify the single most significant barrier to successfully implementing IT solutions intended to improve the patient care process. 34% are indicated that the most significant barrier is a lack of financial support for IT [6].

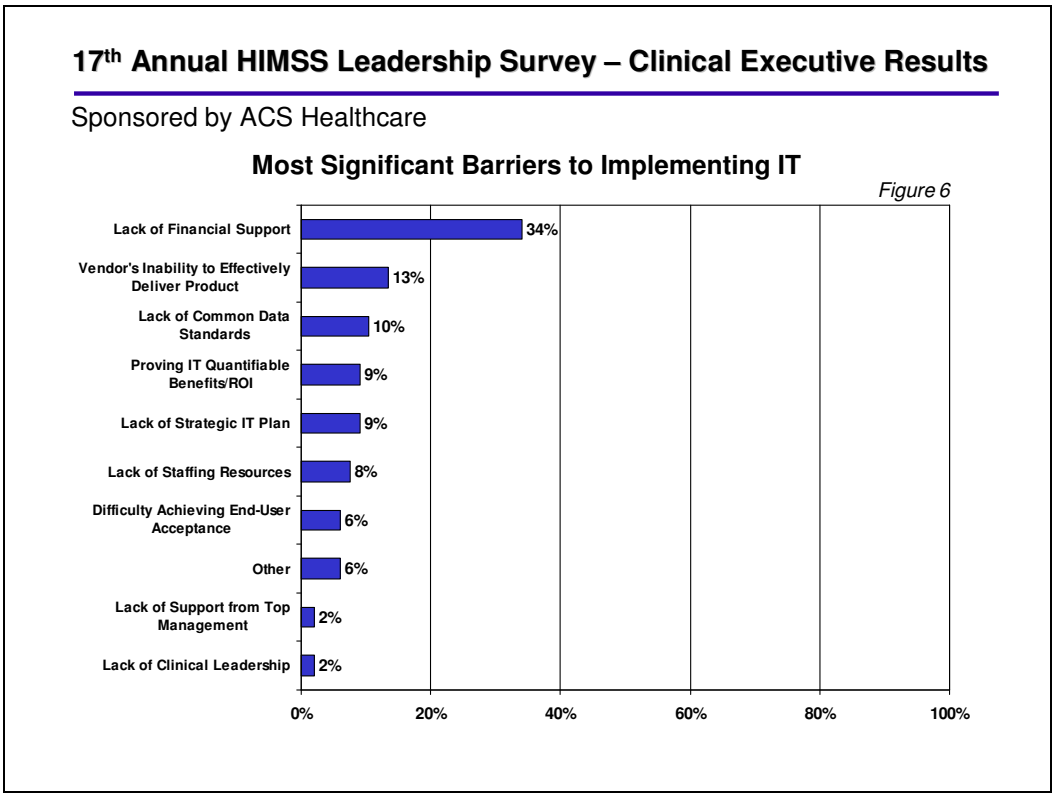


Figure 2.2 Most Significant Barriers to Implementing IT [6].

Also 80% of the respondents in this survey indicated that their facilities IT operating budget would definitely or probably increase for 2006.

Most of the healthcare units are not able to support mid or high level healthcare information systems. Software firms and free lance programmers are charged the units tremendously for the software and after sale support and technical service.

To minimize the cost, cost-benefit and cost-effectiveness evaluation studies should be taken [7]. Programmers should interact with end-users often and discuss the programmed sections. In this way, failures, repetitions, and re-coded parts will be minimized.

It is claimed that the relevance of 'good' health information systems for high-level quality of care is obvious but they are also an important cost factor. Approximately, 10% of the gross domestic products of nations are devoted to healthcare, and approximately 5% to information and communication technology [8].

About 4.6% of the budget of healthcare enterprises is spend on information and communication technology and their failures cause negative effects on patients and staff [7].

Second issue is the implementation difficulties of the software. It is very hard for the health care personnel to change the present system to another computerized system. Also it is difficult for the software programmers to adjust the program such that the previous system and the new one have the same data fields and forms.
The end-users' needs and wants can be infeasible. The end-users are not being able to think the system at the same way.

Another implementation difficulty is the exception handling problem. Every data field needs some exception handling. Exception handling is a programming language construct or computer hardware mechanism designed to handle runtime errors or other exceptions which occur during the execution of a computer program.

Another meaning of exception handling is to arrange the data fields of the database by restricting the data entries with undesirable format. Suppose that there is a data field which should have a date. The programmer must restrict the field for only data entry with

that format. If there is an entry with another format, the system should neglect that data. All fields of the designed system should be controlled in this manner. Since there are numerous data fields in hospital information systems, exception handling takes very long time. Also standardization of data fields and data entered is very difficult.

Software developers should design the system very easy to use. It should not be forgotten that the users are not specialized to use complex systems. The developers should put themselves to end-users position and increase the effective use of the system by make it user friendly. Otherwise the system will not be used properly. If the system is complex, end users will avoid using the system. Also training of users is very costly.

Information systems can be defined as the overall information processing in an organization, including the involved human players and the information technology used. Thus, during IT evaluation, not only the technology itself but also the interaction between IT and human players in their information processing role must be taken into account. Evaluation thus has to consider the environment in which IT is used.

Completing the project on-time and on-budget is a very difficult task. Thus developers should take time for planning. Financial needs should be organized carefully.

Also IT infrastructure of the health care unit is a problem. A server to upload database and other files, an Intranet or at least Internet connection is needed in a hospital. Server should be as fast as possible to handle all applications of the designed system.

System security is a must. Every end user should have their own passwords. Some user restrictions can be applied to the different sections of the system. Thus, every user can reach his/her specific interest area. In this way, both user friendly systems can be provided and more secure, simpler usage of the system is developed.

A computer system or network can be considered secure only when its resources are available to authorized users and when use of those resources produces trusted results [9]. A system compromised by an intruder cannot be trusted. However, software bugs, user errors, or malfunctioning systems are also computer systems security threats. Designing

security into medical information systems is important and should include network connectivity authentication, user name and password management, and update and version control, as well as physical security for the computer hardware.

Computer security threats can be divided into errors of use and design and malicious attacks. Errors of use and design include authorized users making errors (e.g., accidental data deletion) and common software bugs (i.e., erroneous and/or incompletely tested software code). Malicious attacks include unauthorized users, authorized users maliciously viewing or altering data, authorized users knowing or unknowingly giving away passwords, malicious code unknowingly placed on the computer (e.g., viruses, worms, trap doors), denial of service attacks, or unauthorized electronic interception of data and unauthorized physical access to data or systems [9].

2.3 Advantages of Medical Information Systems

To summarize all advantages of Medical Information Systems, main benefits of Health Information Systems are classified into three main groups [10].

1. Clinical Necessity
2. Management Support
3. Market Value

1. Clinical Necessity of Medical Information Systems:
    - help healthcare institute to meet or exceed medical standards of care.
    - affect the quality of care and life quality.
    - improve accuracy, specificity, reliability, timing and safety.

2. Management Support of Medical Information Systems:
    - provide better or more effective decision making.
    - improve operational and maintenance efficiency and effectiveness.
    - decrease dependence on staffing and/or the skill level of personnel and improve staff retention.

3. Market Value of Medical Information Systems:
    - improve access to quality of care.
    - increase customers' convenience and/or satisfaction.
    - enhance organization or service image.
    - improve financial or value impact.
    - reduce cost of paperwork, telephone and other expenses.
    - improve community conditions.

Challenges of Hospital Information Systems and responses to those challenges are grouped as below [11]:

Table 2.1

Challenges of HIS and possible responses to these [11].

Challenges posed by evaluating organisation-wide information systems, and possible responses to these	
Challenge	Response
HIS are usually implemented as part of a complex change/ re-engineering process	Carry out pragmatic, not explanatory studies—but do not claim that the HIS itself caused the benefits
HIS are used by many different professional groups	Seek evaluation questions from each group; answer as many as feasible
Associated with many different impacts	Weight impacts and sum to measure overall impact
Serve real patient care needs	Often implemented incrementally, which provides opportunity for designs such as the externally controlled before–after study (see text)
HIS are ubiquitous, we cannot disrupt live system	Exploit natural experiments—system maintenance, network outages (monitor helpline calls, workload)
It is usually impossible to implement HIS in all parts of an organisation simultaneously	Randomise wards, departments etc. to early or late implementation and make measurements when half are implemented (see text)
Carry over or contamination of HIS benefits from staff training sessions, cross cover, rotations…	Time evaluations to coincide with new junior staff arrival
HIS are multi-functional: admission, discharge, transfer log; order communications, reminders…	Isolate each important function for detailed study
HIS are usually tailored to each organisation	Design evaluation studies to answer the question '*Did this system help here*?' since it is harder to answer the question '*Can HIS help in general*?'

2.4 Medical Equipment Management

Medical Equipment Management defines the mechanisms for interaction and oversight of the medical equipment used in the diagnosis, treatment, and monitoring of patients.

The related policies and procedures govern activities from selection and acquisition to incoming inspection and maintenance of medical equipment. The mission is to ensure that equipment used in patient care is safe, available, accurate and affordable.

It is a management plan describing the processes the hospital uses to manage the effective, safe, and reliable operation of medical equipment.

Medical Equipment Management specifically defines managing risks of medical equipment by ensuring that equipment is used correctly. To minimize risks, that maintainers and users of medical equipment are trained and qualified.

In order to achieve effective, safe, and reliable operation of all equipment in the inventory, hospitals use interval-based inspections and preventive maintenance and corrective maintenance strategies. Medical equipment management process should include an assessment using a multiyear template of when and if equipment will need upgrading, replacement and when new acquisitions are to be added.

A survey is done in three large hospitals in Houston, Texas, with a combined licensed bed capacity of about 1400 beds [10]. The average number of medical devices being used per licensed bed has increased between 1982 and 2002 from 4 devices per bed to over 17 devices per bed. This illustrates that, hospitals are experiencing an increase in the number of medical equipment used per bed.

The primary objectives of the medical equipment management plan are as follows according to EC Standard 6.10 EP 1 [12].

a. Ensuring compliance with applicable regulatory requirements, standards and guidelines, and manufacturers' recommendations.

b. Selecting and acquiring safe medical equipment.

c. Complying with the Safety Medical Devices Act of 1990.

d. Carrying out an effective preventive maintenance program.

e. Providing maintainer and user training.

f. Ensuring back-up equipment is readily available in the event of an equipment failure.

g. Monitoring hazard notices and recalls and providing related information to equipment users.

Medical Equipment Management contains the following activities according to Medical Equipment Management Plan 2006 of Duke University Health System [13]:

1. Selection and acquisition of medical equipment

2. Establishing and using risk criteria for identifying, evaluating, creating an inventory of equipment to be included in the medical equipment management plan before the equipment is used.

3. Identifying appropriate strategies for all equipment on the inventory for achieving effective, safe, and reliable operation of all equipment in the inventory.

4. Defining intervals for inspecting, testing, and maintaining appropriate equipment on the inventory that are based on criteria such as manufacturer's recommendations, risk levels, and current organization experience.

5. Monitoring and acting on equipment hazard notices and recalls.

6. Monitoring and reporting incidents in which a medical device is connected to the death, serious injury and serious illness of any individual.

7. Emergency procedures that addresses:
   - Specific procedures in the event of equipment disruption or failure
   - When and how to perform emergency clinical interventions when medical equipment fails
   - Availability of backup equipment
   - How to obtain repair services

8. Documenting a current, accurate and separate inventory of all equipment identified in the medical equipment management plan.

9. Documenting performance and safety testing of all equipment identified in the medical equipment management program before initial use.

10. Documenting maintenance of equipment, both life support and non-life support, that is consistent with maintenance strategies to minimize clinical and physical risks identified in the equipment management plan.

11. Documenting performance testing of all sterilizers used.

12. Documenting chemical and biological testing of water used in renal dialysis.

Medical equipment effectiveness can be thought of as the system's desired objective "output". Equipment can be seen as "input" [14]. The equipment management program itself is the "system" through which the equipment has entered the program after passing a selection criterion. The following system approach in Figure 2.3 is taken into account.

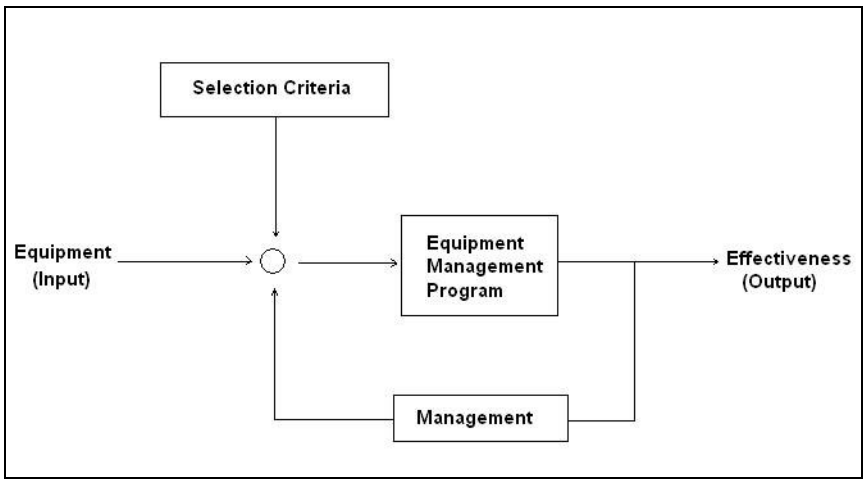


Figure 2.3 A Systems View of Equipment Management [14].

According to the systems view, equipment is viewed as they moved in and out in a clinical engineering department. All new equipment entering the program must be evaluated to determine whether it should be included to the program.

2.5 Medical Equipment Inclusion Criteria

One of the basic requirements for all types of healthcare organizations is that they must design (JCAHO standard EC.1) and provide (JCAHO standard EC.2) "a safe, accessible, effective and efficient environment of care consistent with its mission, services, and law and regulations." One of the components of environment of care management is the obligation to design (JCAHO standard EC.1.8) and implement (JCAHO standard EC.2.7) a "management plan that addresses medical equipment," ensures that "medical equipment is maintained, tested, and inspected" (JCAHO Standard EC.2.13), and "directs an ongoing, organization-wide process to collect information about deficiencies and opportunities for improvement …" related to managing medical equipment (JCAHO standard EC.3.1, intent b)[15].

A central issue within the medical equipment management program is the question of what should be considered medical equipment or, alternatively, which pieces of equipment

should be included in the plan and, thus, “maintained, tested, and inspected.” Realizing that it would be unreasonable to require the inclusion of all equipment within the management program, JCAHO offers the following clarification for the equipment management plan (JCAHO standard EC.1.8):

“The plan provides processes for … (b) establishing criteria for identifying, evaluating, and taking inventory of medical equipment to be included in the management program before the equipment is used. These criteria address:

1. equipment function (diagnosis, care, treatment, and monitoring);
2. physical risks associated with use;
3. maintenance requirements; and
4. equipment incident history.”

Equipment Inclusion Criteria limit the number of equipment included to the program. Almost every clinical engineering professional are using a different interpretation of inclusion criteria for management and maintenance of medical equipment. In the following titles, these interpretations will be introduced.

2.5.1 Inclusion Criteria of Fenningkoh and Smith

Traditionally, most organizations have adopted the equipment inclusion criteria proposed over 15 years ago by Larry Fennigkoh and Brigid Smith [14].

Fennigkoh and Lagerman published a revised version of the original article in the same publication without significant changes, after JCAHO reorganized its standards and incorporated the Plant, Technology, and Safety chapter into the new “functional area” entitled *Management of the Environment of Care* [15].

According to this method of equipment evaluation:

- Each characteristic (equipment function, clinical application, maintenance requirements and equipment incident history) has been broken down into subgroups to facilitate classification of each device type.

- Each subgroup has been ranked and quantified and device types have been assigned a numerical value of each characteristic.

- These values are added to arrive at an equipment management (EM) number used to determine which devices to include in the equipment management program. As will be shown:

$$EM = Function + Risk + Required\ Maintenance$$

Only those devices that have an EM number greater than or equal to 12 are included to the program. However weights of these there parameters are not equal. Function value is given out of 10 and other parameters are given out of 5.

a. Equipment Function: Equipment must be divided into four subgroups according to their function Therapeutic, Diagnostic, Analytical and Miscellaneous as shown in Figure 2.4.

Therapeutic devices generally use electrical or mechanical energy. Therefore they have the greatest risk of injury or death. Ventilators, defibrillators are life support devices. Function values of these devices are assigned as 10. It is followed by diagnostic devices and analytical devices such as laboratory equipment. Devices that are not fitting those three groups are categorized as miscellaneous.

Since the Function constitutes the 50% of the EM number, function values should be significant.

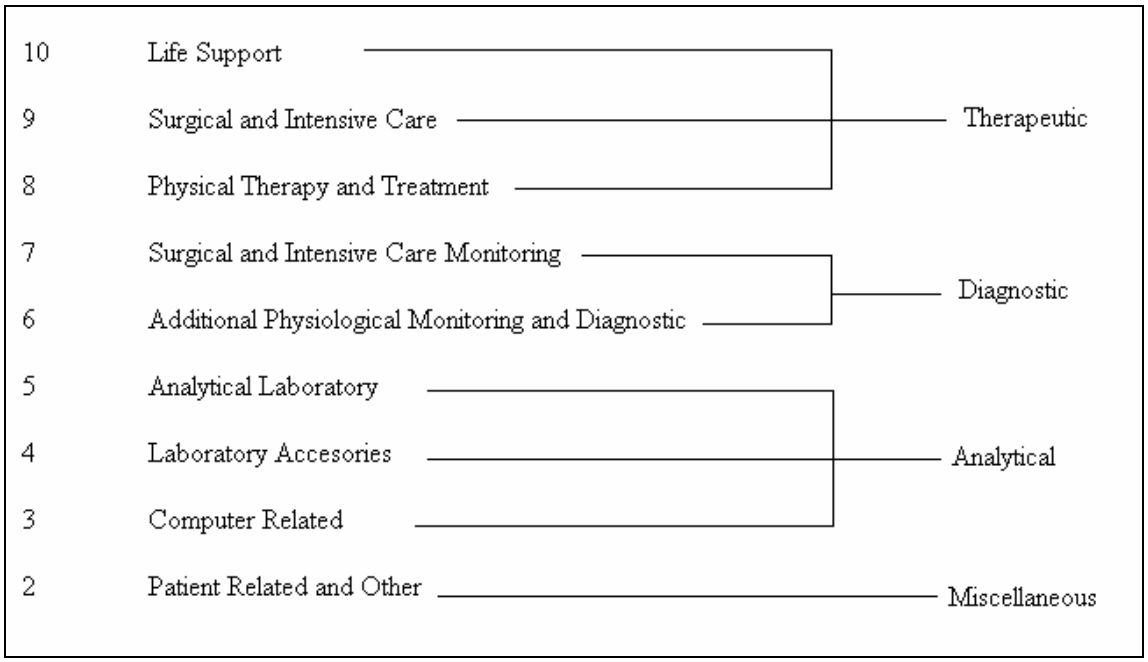


Figure 2.4 Equipment Function criteria of equipment management program [14].

b. Physical Risks: Physical Risks associated with the clinical application of medical equipment are considered according to the possible consequences to the patient and/or the operator in the event of equipment failure or malfunction. Physical risks constitute 25% of the EM number. For example, ventilator malfunction could result with a patient death. Therefore the greatest risk value 5 is assigned to the device. However an electrosurgical unit does not cause a patient death but causes a patient injury.

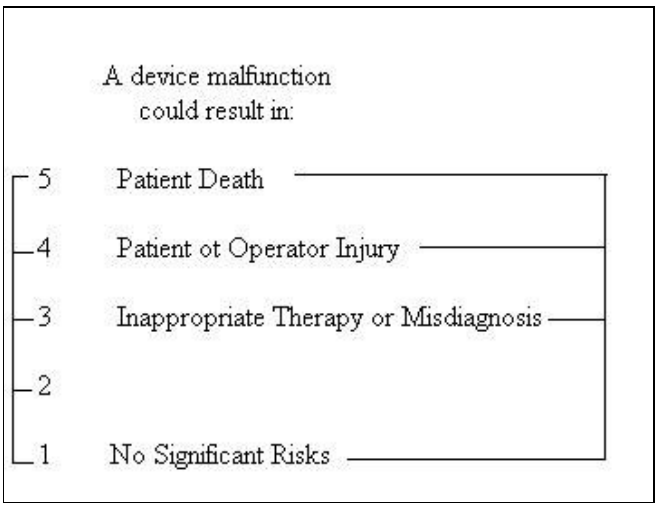


Figure 2.5 Physical Risk criteria of equipment management program [14].

c. Maintenance Requirements: Maintenance requirements constitute 25% of the EM number. It is the part of the EM number which is most difficult to quantify. There are various types of manufacturers and models of same type of equipment. This category is divided into three levels of maintenance requirements: Extensive, Average and Minimal. Equipment that is mechanical, pneumatic, or fluidic in nature has the most extensive maintenance requirements and need routine calibrations, or part replacements such as ventilators and dialysis machines.

Devices that are only need performance verification and safety testing have average maintenance requirements like infusion pumps. Devices that need only visual inspection and basic safety testing have minimal maintenance requirements. Such devices are light resources, laboratory water baths.

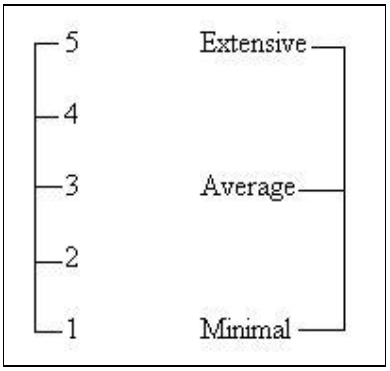


Figure 2.6 Equipment Maintenance Requirements criteria for EM program [14].

The values for each criterion are added to constitute the Equipment Management (EM) number. Devices that have EM number greater than or equal to 12 are included in the equipment management program.

Devices included in the equipment management program will receive Preventive Maintenance (PM) inspection every six months or annually. All PM's are scheduled in this manner. Other devices which are not included to the equipment management program require PM inspection annually.

With this classification system described, the number of devices included to the equipment management program reduced 29%. Also by decreasing frequency of PM inspections (annually instead of every six months), more than 1500 labor hours per year recovered [14].

2.5.2 Inclusion Criteria of Hertz – 1990

A different approach was used by Hertz (1990). He assigned a "severity code" to each piece of equipment by multiplying three relative probabilities:

1) that the equipment will be broken,

2) that the operator will notice that the equipment is broken prior to use, and

3) that the broken equipment will actually cause an injury if it is used.

Then, he computed a “PM index” by multiplying the severity score by the ratio between the time since the device’s last PM and its PM interval. Equipment with a higher PM index would be inspected prior to equipment with lower PM index. Items with low severity codes may have their inspections postponed or never be inspected at all. Medical devices with severity scores medium or high, such as above 5 are generally included to the medical equipment management program.

2.5.3 Classification Scheme of ECRI

Another widely used classification scheme for medical equipment is proposed by Emergency Care Research Institute (ECRI) in 1989 and published in 1995. This scheme is based on a single criterion: “risk of injury resulting from a failure or user error”. Each equipment is classified as a “high-risk”, “medium-risk” and “low-risk” device, according to the consequences of its failure.

ECRI recommends that clinical engineers use this classification to determine the need for inspection and Preventive Maintenance.

2.5.4 New Interpretation of Levenson and Wang

In 1995, Joint Commission on Accreditation of Healthcare Organizations. (JCAHO) completed a reorganization of its accreditation manual for hospitals. One of the important changes in the manual was the introduction of a new function goal called “Leadership”. The goal of leadership function is stated in the JCAHO’s Comprehensive Accreditation manual as “to use a framework to establish healthcare services that respond to community and patient needs”. Leaders are required to develop a mission and vision statements based on prioritization of community needs and internal necessities.

Considering this reorganization recommended by JCAHO, it seems more appropriate to reinterpret the criteria based on “equipment function” as “equipment role and importance within the organization’s mission.”

For example, a defibrillator can be very critical equipment for the survival of a patient; however, it may not be necessary to give the defibrillator the highest priority for inspection or repairs when a sufficient number of working units are available in the hospital. On the other hand, although not being a life support device, the blood- gas analyzer in the hospital cannot be stay nonfunctional for a long time. Otherwise, number of patients will be left without proper diagnosis or monitoring.

A new inclusion criterion is proposed by Levenson and Wang with this basis [15]. According to this interpretation, each piece of equipment is assigned a value ranging from 1 to 10 based on the judgment of how critical the function of the equipment. This value is called "Mission Critical".

Mission Critical value is then used for deriving "Equipment Management Rating" (EMR) by using the following Formula:

$$EMR = \text{Mission Critical} + 2 * \text{Risk} + 2* \text{Maintenance}$$

where Risk values were derived from ECRI's risk classification, substituting high risk (H) with 5 , medium risk (M) with 3 and low risk (L) with 1, and maintenance values were same as those used in Fenigkoh and Smith interpretation.

The minimum and maximum values for EMR are 5 and 30. The multiplication factor of two is introduced to provide equal weight for all three parameters, rather than giving a higher weight to the mission critical criterion.

The most important parameter which is not considered for this interpretation is the number of units of each device type. As it is previously mentioned, it is not very crucial to repair a defective defibrillator, if there are multiple units of defibrillators. However it is not efficient to simply count the numbers of each device type. Demand may be greater than supply. Levenson and Wang considered a "Utilization Rate" of each device type which is the average percentage of time each type of equipment is being used and included it into the formula:

$$\text{Adjusted EMR (AEMR)} = (\text{Mission Critical} + 2*\text{Maintenance})*\text{Utilization} + 2*\text{Risk}$$

Where maintenance and risk values are the same as previous version, and utilization is utilization rate percentages, chosen by the authors.

In the following table, comparison of Fennigkoh and Smith's inclusion criteria and Levenson's Equipment Management Rating is shown for a list of medical equipment chosen. Mission critical values and utilization rates are also listed.

Table 2.2

Classification scheme considering mission critically and utilization rate [15].

Device	F&S EM#	ECRI Risk	Mission Critical	EMR	Utilization (%)	AEMR
CT scanner[1,2]	14	H	10	30	85%	27
Automatic analyzer (clinical lab)[1]	13	M	10	26	100%	26
Cath lab[1,2]	18	H	9	29	75%	24
Sterilizer (steam, EtO, etc.)[1]	9	H	8	24	95%	23
Gamma camera[1,2]	14	H	9	29	65%	22
Hypo/hyperthermia	18	H	6	26	75%	22
Ultrasound scanner[1]	14	M	9	25	85%	22
[Intra-aortic] Balloon pump	20	H	9	29	50%	19
Ventilator	20	H	9	29	50%	19
Infant incubator	19	H	8	26	60%	19
Blood pressure amplifier [invasive]	13	H	7	23	75%	19
Physio[logical] Monitor	13	H	7	23	70%	19
Hematology analyzer[1]	12	M	8	22	85%	19
Infusion pump	14	H	8	22	60%	17
Treadmill	17	M	5	21	75%	17
Blood bank refrigerator[1]	11	M	8	20	85%	17
Fetal monitor	12	H	7	23	50%	16
Electrocardiograph	13	M	6	20	75%	16
Pacemaker [external]	19	H	8	26	35%	15
Centrifuge	12	M	5	21	60%	15
Defibrillator	19	H	10	28	12%	12
Diathermy	16	L	5	15	80%	12
Ultrasound, Doppler[2]	10	M	5	13	50%	9
Terminal [computer/video][2]	5	L	4	8	80%	6
Water bath	7	L	2	8	75%	6
Surgical lights[1]	13	L	4	8	65%	5
Exercise weight (physical therapy)[1,2]	12	L	2	6	75%	5
Exam light[3]	4	L	2	6	60%	4
CPR mannequin[2,3]	4	L	3	7	35%	3
Scale [general patient care]	7	L	3	9	12%	2

[1] Device not listed in Fennigkoh & Smith (1989). Values assigned by the authors following the suggested interpretation.

[2] Device not listed in ECRI (1990). Levels assigned by the authors based on the suggested rules and examples provided.

[3] Fennigkoh & Smith (1989) erroneously stated that the EMs for these devices were 3 instead of 4.

2.5.5 Gullikson and Yadin's Dynamic Risk Assessment Tool

In 1993 and 1996 Gullikson and Yadin is expanded the Fennigkoh and Smith's interpretation by introducing a dynamic criteria [15].

Dynamic Risk Assessment Tool consists of four modules which are either dynamic or static risk characteristics. Static components are equipment function and physical risks which are assigned to medical equipment. These two components are the same with components in Fennigkoh's formula except for a change in their maximum values [16].

The two dynamic components are the maintenance requirements and the risk points. The maintenance requirements measure works on an assumption that an increase in number of interventions by technicians both causes and indicates risk.

The risk point combines various risk factors such as actual failures and reasons of failure.

The output of each factor is summed and average over a six-month period, rated from 1 (low) to 5 (high). A feedback loop permits the clinical engineer to review equipment that shows an increase in risk over a predetermined period of time.

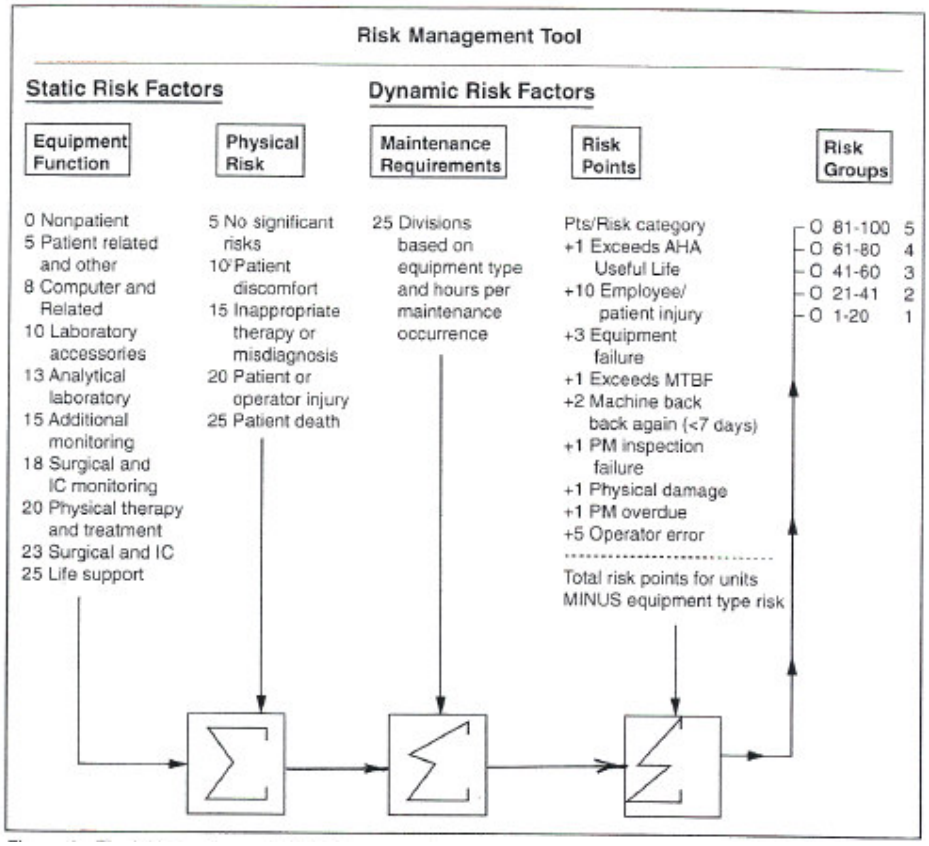


Figure 2.7 The initial assignment of risk factors [16].

2.5.6 Simplified Gradient Risk Sampling of Wang and Rice

Gradient Risk Sampling (GRS) is based on an assumption of each equipment has a benefit and a risk to the healthcare organization. High risk equipment requires greater assurance of continued proper operation than low-risk equipment hence more safety and performance inspections (SPI). It is shown that this requirement results, under the assumption of limited resources, in a sigmoid relationship between the SPI sampling requirement and the risk measure which is EMR or AEMR [17].

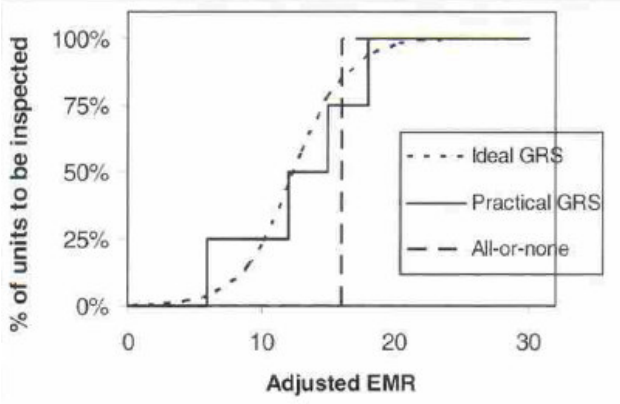


Figure 2.8 Example of Gradient Risk Sampling versus all-or-none approach [17].

It is possible to use a step-wise function to implement simplified GRS by approximating the sigmoid function shown in Figure 2-8. It is established by dividing the inventory into different risk groups using EMR or AEMR. The percentage of groups decrease from the highest to the lowest, starting at %100 to zero.

In the traditional all-or-none approach, all units above a certain threshold AEMR are inspected and none are inspected below AEMR threshold.

In this approach, it is reminded that each organization should make its own decision on how to choose the sample percentages and AEMR thresholds. There are no restrictions or rules about sample percentages.

Device	Mission Critical	EMR	Utilization (%)	AEMR	% Units to be Inspected
CT scanner	10	30	85%	27	100%
Automatic analyzer (clinical lab)	10	26	100%	26	100%
Cath lab	9	29	75%	24	100%
Sterilizer (steam EtO etc.)	8	24	95%	23	100%
Gamma camera	9	29	65%	22	100%
Hypo/hyperthermia	6	26	75%	22	100%
Ultrasound scanner	9	25	85%	22	100%
[Intra-aortic] Balloon pump	9	29	50%	19	100%
Ventilator	9	29	50%	19	100%
Infant incubator	8	26	60%	19	100%
Blood pressure amplifier [invasive]	7	23	75%	19	100%
Physio[logical] Monitor	7	23	70%	19	100%
Hematology analyzer	8	22	85%	19	100%
Infusion pump	8	22	60%	17	75%
Treadmill	5	21	75%	17	75%
Blood bank refrigerator	8	20	85%	17	75%
Fetal monitor	7	23	50%	16	75%
Electrocardiograph	6	20	75%	16	75%
Pacemaker [external]	8	26	35%	15	75%
Centrifuge	5	21	60%	15	75%
Defibrillator	10	28	12%	12	50%
Diathermy	5	15	80%	12	50%
Ultrasound Doppler	5	13	50%	9	25%
Terminal [computer/video]	4	8	80%	6	25%
Water bath	2	8	75%	6	25%
Surgical lights	4	8	65%	5	0%
Exercise weight (physical therapy)	2	6	75%	5	0%
Exam light	2	6	60%	4	0%
CPR manikin	3	7	35%	3	0%
Scale [general patient care]	3	9	12%	2	0%

Figure 2.9 Example of application of simplified Gradient Risk Sampling [17].

However there are some disadvantages of this approach. Simplified GRS is a better approach for equipment types that have between 15 and 50 units. If it samples too few equipment, it can not provide high enough statistical confidence level. When there are more than 50 units, the simplified GRS approach can require far more samples than actually needed for a given confidence level and waste time and resources. First disadvantage can be addressed by increasing the sample size but the second one is more serious.

2.6 Risk Management and Risk Classification

Risk Management is defined in ISO 14971 as the systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating and

controlling risk [18]. A risk can be a side-effect, device defect, device use error or another uncertainty about a medical device and its effective use.

ISO 14971 sets out a procedure for risk management by dividing risk management into 4 subgroups: Risk analysis, risk evaluation, risk control and postproduction information.

Risk analysis is the list of hazards and misuses of medical equipment in normal and faulty conditions. For each hazard listed, the associated risk must be estimated. In risk evaluation, the estimated risk of medical equipment is accepted if it is below a certain acceptability threshold or a risk reduction procedure is applied.

Risk control contains identifying and implementing control measures for risk reduction. Once control measures are implemented and risks are identified, a further risk-benefit analysis should be conducted. Also it is very important that risk management process should be documented as a risk management report.

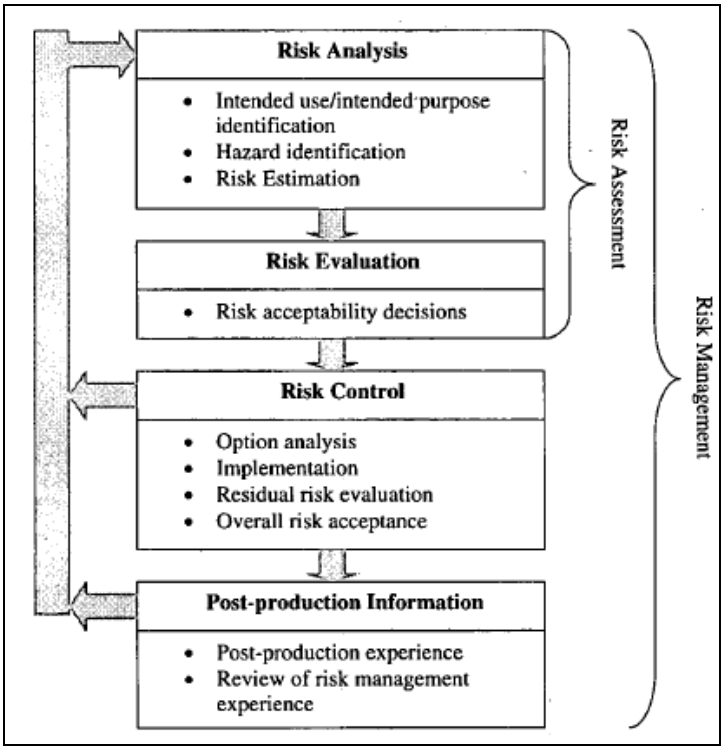


Figure 2.10 Risk Management Procedure

In the previous chapter, it is shown that there are different approaches for medical equipment inclusion for the Preventive Maintenance program. Many of the approaches are based on the parameters proposed by Fennigkoh and Smith which are functional risk, maintenance requirements and physical risks.

However, there is a limitation in such proposal. The risk classification of medical equipment does not change during the period of their utilization. The risk classification of medical equipment can increase depending on quality of management, aging, time used etc. Therefore a risk factor should be included to the equipment management program. Risk factor indicates the existence of some situations to the occurrence of equipment failure.
For the risk classification, a risk estimation concept is used [19].
ISO 14971:2000 Standard recommends the use of the "qualitative method of risk estimation" [19]. In Table 2-3 discrete levels of harm severity, hazard frequency are defined and attributing weights of each level is defined.

Another parameter is "risk tolerance". Depending on the risk value, risk tolerance can be considered as acceptable (no need to risk reduction procedure), tolerable (the risk is above an acceptable value but it is still possible to use medical equipment within minimal safe conditions) or unacceptable (obtained benefits of medical equipment do not compensate its risk).

Table 2.3

Qualitative Estimate of Risk [19].

Risk = Weight (Severity) x Weight (Frequency)				
Frequency	Severity			
	Catastrophic (W=4)	Critical (W=3)	Marginal (W=2)	Slight (W=1)
Frequent (W = 4)	16	12	8	4
Occasional (W=3)	12	9	6	3
Rare (W=2)	8	6	4	2
Remote (W=1)	4	3	2	1

Harm Occurrence Frequency Levels:

-Frequent: can occur within a short period (more than 2 times a year)

- Occasional: Probable of to happen (2 times a year)

-Rare: Possibility of happening (once a year)

-Remote: very improbable to happen (no occurrence registered)

Harm Severity Levels:

Catastrophic: possibility of death or major permanent loss of function (motor, sensory, physiologic, or intellectual)

-Critical: possibility of permanent lessening of bodily functioning (motor, sensory, physiologic, or intellectual)

-Marginal: increased length of stay

-Slight: no injury

Acceptable estimated risk levels :

-Dark gray: unacceptable risk

-Light gray: tolerance risk

-White: acceptable risk

An important part of risk analysis is, understanding how critical an unsafe condition might be. A risk index is a derived value that depends on the probability and the severity of the hazard. Four risk indexes are proposed [19]. The resultant risk R_{RE} is equal to the sum of all risk indexes and formulized as:

$$R_{RE} = R_{SIR} + R_I + R_F + R_{EST} \quad \text{where}$$

R_{SIR} = represents the risk of hazards related to ME failure notifications detected during the safety inspection routines.

R_I = represents the risk deriving from external notification of incidents with the same types of ME that are used in the hospital.

R_F = represents the risk associated to the existence of risk factors in the hospital:

R_{EST} = represents the estimated risk with the highest value among all the detected hazards.

In Table 2.4, an example of calculation of risk estimation is given for a cardiac defibrillator.

Table 2.4

Table of Risk Indexes for Cardiac Defibrillator [19].

Risk Index R_{SIR}	Hazards	Severity Levels
	"not supply of energy for defibrillation"	Catastrophic
R_{SIR} = 16		
Risk Index R_I	External Incidents	Severity Levels
	Not-notified incident	-
R_I = 0		
Risk Index R_F	Risk Factors	Weights
	Successive corrective maintenances in the same Medical Equipment	3
	Utilization of batteries with speared time of discard	3
R_F = 6		
Risk Index R_{EST}	Hazards	Estimated Risk
	"not supply of energy for defibrillation"	12
R_{EST} =12		
$R_{RE} = R_{SIR} + R_I + R_F + R_{EST}$ = 16 + 0 + 6 + 12 = 34		

R_{SIR} = 16 since the severity level of harm is Catastrophic.

R_I = 0 since no incident was registered by Food and Drug Administration with the same type of medical equipment that are used in the hospital.

R_F = 6 since the estimated risk is unacceptable for given risk factors.

R_{EST} =12 since Estimated risk = 4 (catastrophic) x 3(occasional) = 12

The indexes are graded in 3 alert levels which are represented with three colors:
Green: Continue with the actual safety procedures.
Yellow: Attention with the safety conditions of medical equipment utilization.
Red: Urgency to apply the risk control procedures.
When there are more than one alert level present for the risk indexes, to worst alert level is valid.

Therefore a medical equipment group can be graded as a color coded alert indicating a necessity of implementing risk control procedures for reduction of resultant risk.

2.7 Medical Device Problems and Medical Equipment Management

Patients generally rely on physicians, nurses or therapists during a hospital stay but not the biomedical engineering staff. The patient will not even suspect the existence of biomedical engineering staff. It is questioned: “Why then is JCAHO accreditation focused on the equipment rather than on the manner in which the equipment is operated and treated by these clinicians [21]?”

UK’s equivalent of FDA, the Medical Devices Agency (MDA), received nearly 9000 reports of medical device incidents and accidents in 2002 [3].

About 1500 of these posed “serious safety implications” which prompted MDA investigation. About 200 patients died resulted from these incidents, 40 were determined by MDA to be due to medical device failure. There was no clear pattern in the cause of many of the problems. Some were found to have been caused by design faults and others by human error.

In February, 1996, the Emergency Care Research Institute (ECRI) summarized the reporting requirements mandated by the Safe Medical Devices Act. According to that report: “Healthcare facilities must submit a report whenever they receive or otherwise

become aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to a death or serious injury [21]."

However there are so many uncommitted injuries in hospitals. Safety issues are very important. There are thousands of medical devices used and nobody reads the operating manuals. The percentage of risks are needed to understand how safe is really safe. Let's say 0.1% or 0.01% accidents mean safe for surgical procedures. There are 20 million surgical procedures are performed annually in United Kingdom [21]. This low risk percentage becomes 20,000 or 2,000 accidents. These are really large numbers that should be taking care of.

According to FDA, medical device problems usually fall within one of three main categories:

1. Device problems, including malfunctions, manufacturing and material problems.
2. Use problems, including appropriateness, design, training, labeling, and packaging.
3. Clinical problems including those directly attributed to device and use problems, as well as preexisting conditions that make the device risky to use, allergic reactions to a device, or other therapeutic challenges [22].

Every device problem can result with a patient injury, user or operator injury or even worse patient or operator death. Therefore medical equipment failures should be identified in detail, reasons of failure and effects of failure should be analyzed and potential error situations should be evaluated.

Complexity of new medical equipment devices is another issue of medical device problems. The new equipment tends to be more complex than earlier generations. Most of the pieces are used software programming. The increasing use of software programming to manage the function of medical equipment adds a new dimension to the assessment of equipment at the time of purchase or introduction. The dimension is complexity [23].

The need for a medical equipment management program became evident when the following problems are encountered [10].

- Recently purchased equipment not sufficiently used.
- On-going user problems with equipment.
- Excessive downtime and ownership cost.
- High percentage of equipment failing and awaiting repair.
- Maintenance costs
- Medical equipment upgrading, replacement and planning are not intertwined.

Medical equipment management may be the degree to which care providers are challenged to prove they have the necessary clinical knowledge, clinical judgment, and technical skill to apply equipment safely and effectively as part of a medical procedure.

2.8 Planning the Preventive Maintenance of Medical Equipment

Many medical equipment items need periodic attention to ensure that they continue to operate properly and safely. Some devices are critical than others. It is accepted that there is a lack of consensus on how to determine which devices should be included in this critical device category and which can be excluded from this periodic attention. This periodic attention is basically called “Preventive Maintenance” or “PM”.

Preventive maintenance is defined as a planned maintenance of medical equipment that is designed to improve equipment life and avoid any unplanned maintenance activity. PM includes cleaning, lubrication, adjusting, and minor component replacement to extend the life of equipment [24]. The primary objective of the preventive maintenance is to avert predictable and preventable device failure.

Since the equipment failure can interest both the patients and the hospital as well, preventive maintenance is a very important mission of a healthcare facility and clinical engineering department.

Equipment used for any kind of medical procedure should be held to a higher standard than other types of equipment [24]. Inadequately maintained medical equipment creates an unacceptable risk of patient injury, and this is the reason that the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) has created special requirements for the maintenance of such equipment. JCAHO's standard EC.2.10.3 states that, performance and safety testing should be conducted at least annually.

The best source for information on which of the device's components need periodic attention, and on what the procedure for that attention should be, is the device manufacturer. The information should be contained in the documentation provided with the equipment. Therefore documentation and manuals of medical devices should be carefully read by clinical engineering department.

Typical preventive maintenance intervals are 6 months and 12 months. By considering the device failure frequency this interval can be changed. Devices that should be included in a monitored maintenance program are those that meet the following two criteria [24]:

1. Devices that are critical devices in the sense that they have a significant potential to cause injury if they do not function properly.

2. Devices that are maintenance sensitive in the sense that they have a significant potential to function improperly if they are not provided with an adequate level of PM.

In order to establish an effective, efficient preventive maintenance system, filing systems are needed either computerized or not. All equipment in the hospital should be recorded with a referenced number. Therefore an inventory of hospital will be created. Then intervals of preventive maintenance are determined. Once the equipment has been inventoried, the preventive maintenance programming should be created. It may be necessary to develop a reminder system, so that appropriate personnel are notified about

the preventive maintenance intervals. People responsible for equipment management and maintenance should check the correct functioning of medical equipment.

Inventory database will contain historical repair information as time goes by. The value of this data will be apparent in the equipment management and replacement process. Two main pieces of data are the number of failures since the item was put into service and the cumulative cost of repairs.

2.9 Preparing Medical Device Inventory

As it is said before, the first step of planning the preventive maintenance and medical equipment management plan is creating a medical equipment inventory of the healthcare unit. It is a very long and difficult process but without having the inventory none of the manual or computerized management systems can be used.

Inventories enable organizations to effectively analyze medical equipment. By using hospital inventory and management tools together, clinical engineers increase the accuracy of data capture and facilitate the physical handling of medical devices.

All equipment in the hospital that is in the care of the service workshop should be recorded on inventory system. Inventory system can be an Excel sheet or a professional database.

First step when preparing the inventory is to give a unique registration number to all medical devices. This number is called Biomedical Inventory Number. It contains 11 or 12 alphanumeric characters. Generally this number is composed of a special medical device code, service code and sequence number of the device.

ECRI (the Emergency Care Research Institute) is developed a standard for medical device codes called UMDNS (Universal Medical Device Nomenclature System).

UMDNS is a standard international nomenclature and computer coding system for medical devices. It is the worldwide nomenclature that has been officially adopted by

many nations. It is used in ECRI's databases and publications, as well as in thousands of healthcare institutions worldwide.

The purpose of UMDNS is to facilitate identifying, processing, filing, storing, retrieving, transferring, and communicating data about medical devices. It contains nearly 7,500 unique medical device concepts and definitions. UMDNS code contains five characters. For example 10208 is the UMDNS code of Aspirators.
Service code is three or four characters long and it symbolizes the service that the equipment is used. For example, for Intentive Care Unit, "ICU" is used.
Sequence number shows the number of same type of device in the same service.

As a whole, biomedical inventory number will differentiate every medical device even if their brand name or model is the same. Other important parameters that should be included to the inventory registration are medical equipment suppliers' contact information, equipment model and serial number details, preventive maintenance details, service that the equipment is in use and contact information of personnel that is in charge of the equipment. That information can be increased according to needs of clinical engineering department.

2.10 Parameters Used in Medical Equipment Management

Preventive Maintenance studies are generally resulted with some statistical data about history of repair and failures. These data are guidelines of clinical engineering departments. By analyzing the results of PMs, forward-looking information about medical equipment are achieved and clinical engineers decide on replace the equipment or not. In addition to the most important two values that are informed before, other statistical values are as follows:

1. Number of Repairs: Number of repairs on a particular device within a specified short period of time. It gives information about number of failures. These failures could be caused by age, poor design, user error, or another reason. More repairs mean the medical device is more likely to being replaced.

2. Cumulative Cost of Repairs: It is the total cost of repaired parts of the medical equipment. Every repair, every part that is changed has a cost. This cost can be easily determined by using a PM program. If the cumulative cost of repairs is greater than the normal price of the equipment, the equipment should be replaced. Sometimes small part replacements are very costly when the failure is repeating.

3. Repair Cost Factor: Repair Cost Factor is basically formulized as

   Repair Cost Factor = Cumulative cost of Repairs / Acquisition Cost

   Acquisition cost can be defined as price that medical equipment is bought. Repair cost factor is theoretically between zero and infinity but in real world it is a number which is between zero and two [25]. However it is obvious that the repair cost factor should be as low as possible.

4. Downtime: It is the amount of time that a system or medical device is down and not available to perform its primary function [9]. Downtime causes loss of patient and also loss of money. Downtime of a device can be calculated by subtracting the time the device is out of service from the time that device is repaired and up again.

5. Age Factor: Age Factor is formulized as

   Age Factor = Age / Life Expectancy

   Age is the current date minus the date that the equipment is put into service. Life expectancy is the expected life of the medical equipment. In most cases, expected lifetime of the device is given in the documentation of device.

6. Turnaround time: It is the time from initial call of failure to final repair. This parameter also shows the service quality of the vendor or the manufacturer.

2.11 Medical Equipment Replacement Management

A biomedical equipment management database is a beneficial tool to keep medical equipment information. Some important parameters such as Age Factor and Repair Cost Factor are calculated from entered data to the database. Most of the time, clinical engineering department has no time to analyze these valuable data. By using a database, automatic generation of calculated data fields is provided.

Designed database keep historical repair information. This information is very valuable for a manager who involved in medical equipment management and replacement management processes. Two important data is obtained from the database and wil be observed in detail. Number of failures since the item was put into service and cumulative cost of repairs.

Whether the failure of an item is a hard failure or a very simple failure, it causes a delay in the work order. If a medical device fails more often than another, a biomedical engineer can easily identify it from the database. These failures could be caused by age, poor design, user error, or a host of other reasons. In the case of very frequently repeated failures, sometimes replacement of a device can be a better solution. Also in some cases, a replacement of the equipment can be taken into account without any failure because of the increased age of the medical equipment. A replacement planning methodology can be applied.

The bottom line for the replacement methodology is failure rate. The more often the device fails, the higher the likelihood that is should be replaced. The second data is the cumulative cost of repairs. Every repair of medical equipment adds another cost into equipment's data field in the database. Repeated failures mean more cost. On the other hand, equipment becomes spending more time in the repair than in use. If the costs of repairs exceed a certain value, a replacement of medical equipment can be considered.
These two factors combined with the age of the medical equipment represent three quantifiable and objective factors that are used for the replacement management [25].

There are also other factors which are subjective. Subjective factors are evaluated using Lakert scale. This scale runs from one through some odd number, usually through five or seven and is used to quantify opinions using scales such as "Disagree (1), Somewhat Disagree (2), Neither Disagree nor Agree (3), Agree (4), Strongly Agree (5)" [25].

The first subjective factor is the advancements in technology. Between the dates the device is first bought and today, there can be technological improvements in that field. For example replacing a conventional ethylene oxide sterilizer with a plasma sterilizer is a technological advancement.

The other subjective factor is an evaluation of how well replacement of a particular item fits into the organization's five year plan. This factor depends the imagination and experience of the biomedical engineer. These five factors are weighted as shown in table below:

Table 2.5

Replacement Evaluation Factors and Weights

Factor	Source	How Determined	Weight
Age Factor	Simple Methodology	Age / Life Expectancy	1.0
Repair Workorders	From Database	Number from database	0.5
Repair Cost Factor	From Database	Cumulative cost of repairs/ Equipment cost	2.0
Advancements in Technology	Evaluation of replacement item	Subjective evaluation	0.5
Fit into Five Year Plan	Evaluation of 5 year plan	Subjective evaluation	0.75

After determining given factors, a number called Order Merit Number is developed. It is based upon an assessment of the individual weighted factors. It is the sum of the weighted evaluation factors; each weighted factor is comprised of the factor times the weighting factor. It can be formulized as [25]:

Order Merit number = [Age (in years) / Life Expectancy (in years)] x 1.00 +
[Number of Repair Work orders] x 0.50 +
[Cumulative cost of Repairs /Equipment cost] x 2.00 +
[Evaluation of Advancement in Technology] x 0.50 +
[Evaluation of the Fits into Five Year Plan] x 0.75

If medical equipment replacement table is listed according to Order Merit Number, the larger the Order Merit Number is the first medical equipment that should be replaced.

3. METHODS

As indicated in theory part, many problems may be faced during implementation of software for medical equipment management system. Software projects are mostly failed due to various reasons. The system should be accurately analyzed, planned and then applied to the healthcare institute. The objective of this study was to determine the possible implementation solution of a medical equipment management system for a healthcare institute. The main reason of planning this system is to make medical equipment controls, preventive maintenances, inventory controls, analysis and statistical information easier and organized.

The initial step of the process is the choice of organization to apply the medical equipment management software. After that, inventory of healthcare institute and preventive maintenance and calibration programs are developed. By using obtained data of the hospital inventory and preventive maintenance calendar, software is analyzed, designed, planned and compiled. The last part of the study is testing of system in the healthcare institute. If the tests successfully end, project is completed. If they fail, system is once more controlled according to the user feedbacks.
In this part, all of these steps are explained in detail.

The system is designed in an easily modifiable way. Therefore it can be used in any healthcare unit with a small change on the system inventory.

As a result of some surveys and discussions with biomedical engineering department, it is understood that a computerized system to control inventory and preventive maintenance schedule automatically is necessary. Biomedical engineers were complaining about control the inventory easily and plan the PM intervals accurately.

3.1 Medical Equipment Management System Parts

The software system is planned as a web based system which can be used online from an Internet site. With a web based design, the system will be used from every department of the healthcare unit. Firstly, a common website design is planned, a program name and logo is created. Program name is chosen as MEMS, “Medical Equipment Management System”. Program logo is created with a special logo creator program.
The content of the system is planned with the help of biomedical engineering department and the thesis advisor.

The System is planned on seven different parts.

1. Medical Equipment Registration Management

   This part is used to register new medical equipment to the inventory. It has some sub parts such as warranty information, equipment identity information and medical inventory of assets in the healthcare unit. Users also refer to ECRI’s UMDNS codes list from this section.

2. Failure Registration Management

   Failure Registration is a part to enter medical equipment failures, to follow the last condition of the equipment, and failure results. Users can enter important notes in every step until the failure is solved. Most frequently failed devices can be listed and their maintenance and calibration period can be changed by the user in this section.

3. Personnel – Equipment Assignment

   It is used for personnel registration to the system that is in charge of medical devices. Personnel telephone number, department, home address is entered to the system.

4. Calibration / Preventive Maintenance Management

   It is the most important part of the system. Creation of calibration and PM schedule is under this part. Also medical equipment that is failed from Preventive Maintenance is

listed in this section. Users can create annual calibration schedules. Equipment Maintenance value of an equipment can be entered and modified.

5. Safety and Performance Inspection Management

Safety and Performance Inspections are provided in this section. Every medical device has its own safety and performance inspection forms created and uploaded by biomedical engineering department. In a desired period, forms can be downloaded, filled and re-uploaded to the system. System is capable of keeping unlimited numbers of inspection forms to the system. Also medical equipment acceptance testing is available in this section.

6. Medical Equipment Risk Management

This part is generated according to the risk management procedures that are discussed in section 2.6. Risk Management and Risk Classification. For each equipment in the inventory Risk scores are given by the users. Therefore risk classification of medical equipment and risk colors are obtained.

7. Medical Equipment Replacement Planning

Replacement planning of medical assets of the healthcare unit is evaluated in this section. Clinical engineers and biomedical engineers decide on which devices should be replaced because of frequent failures or high cost of repairs and which are going to be used.

8. Analysis and Graphical Representations

Graphical information such as medical equipment failure frequencies, mostly occurred failure reasons, repair cost analysis and downtime analysis.

9. User Operations

User operations are user dependent pages such as system password changes. Admin assigns a password for all types of users. Users can enter the system with that password and then can change his/her password from this part later.

3.2 Database and Inventory Preparations

Database is created in Microsoft SQL Server. As a first thing, the inventory is simulated with a couple of inserted medical equipment.

User definitions are planned. One admin user is created who have all rights to access and change the system. Other users are basic users who have rights to only access special parts of the system.

Database is planned according to the software engineering rules. Sub tables are joined with main tables. In many of the tables of the database, Biomedical Inventory Number which is a unique number contains 11 characters, is used as a primary key of the table. All fields are shown with their names, data types such as integer or character and lengths.

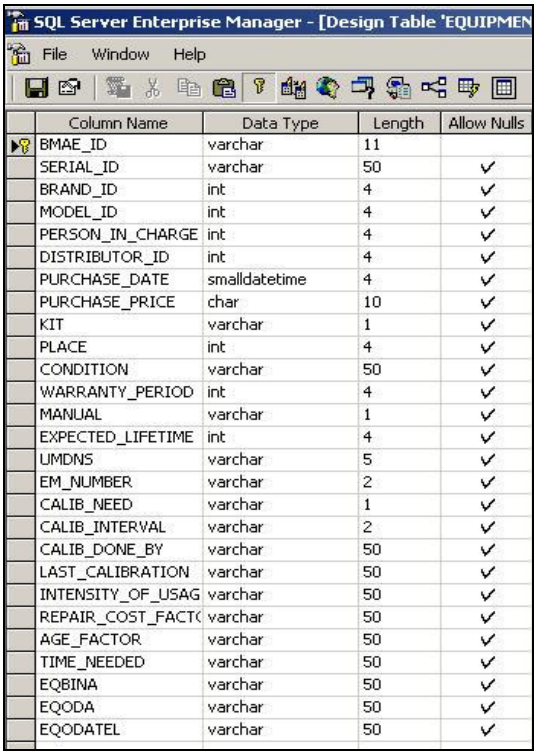
3.3 Implementation

After planning the whole database tables according to the inventory, calibration and preventive maintenance schedules, the database tables are created. Let's give some brief information about important fields of the inventory table.

BMAE_ID is the unique biomedical device inventory number such as 01S 17591 001. The first three characters are designed to show hospital department. In this example 01S shows the hospital department or floor that the medical equipment is placed which is first floor. The middle five characters 17591 is the UMDNS code of the device. In this case 17591 is the code of resuscitators. 001 part shows the sequence number. That means this device is the first resuscitator in the floor.

Table 3.1

Equipment Inventory Table from MEMS Database.



Column Name	Data Type	Length	Allow Nulls
BMAE_ID	varchar	11	
SERIAL_ID	varchar	50	✓
BRAND_ID	int	4	✓
MODEL_ID	int	4	✓
PERSON_IN_CHARGE	int	4	✓
DISTRIBUTOR_ID	int	4	✓
PURCHASE_DATE	smalldatetime	4	✓
PURCHASE_PRICE	char	10	✓
KIT	varchar	1	✓
PLACE	int	4	✓
CONDITION	varchar	50	✓
WARRANTY_PERIOD	int	4	✓
MANUAL	varchar	1	✓
EXPECTED_LIFETIME	int	4	✓
UMDNS	varchar	5	✓
EM_NUMBER	varchar	2	✓
CALIB_NEED	varchar	1	✓
CALIB_INTERVAL	varchar	2	✓
CALIB_DONE_BY	varchar	50	✓
LAST_CALIBRATION	varchar	50	✓
INTENSITY_OF_USAG	varchar	50	✓
REPAIR_COST_FACT(	varchar	50	✓
AGE_FACTOR	varchar	50	✓
TIME_NEEDED	varchar	50	✓
EQBINA	varchar	50	✓
EQODA	varchar	50	✓
EQODATEL	varchar	50	✓

SERIAL_ID is the serial number of the medical equipment. Brands of the medical devices in the hospital are created in Brands table. BRAND_ID is the primary key of the Brands table.

MODEL_ID is the primary key of the pre-designed Models table like Brands table.

PERSON_IN_CHARGE is the name of the person who is in charge of that medical equipment. DISTRIBUTOR_ID is the primary key of the Distributors table. It shows the distributor names of the medical devices.

PURCHASE_DATE and PURCHASE_PRICE are the date of purchase and price of purchase of the medical equipment. These are necessary to calculate the lifetime of the medical equipment and cost of repair.

CONDITION shows if the device is in used or in service or is not in used for any other reason. EM_Number is the equipment management number which is described

before. It is a number up to 20 which is the addition of function, risk and maintenance requirements values of medical equipment. It is an inclusion criterion for medical devices. CALIB_NEED shows the calibration need of devices. It is simply 0 (no need for calibration) or 1 (need for calibration). CALIB_INTERVAL is the predefined calibration interval of the equipment. It can be 6 months, 12 months or else. LAST_CALIBRATION is the date of last calibration that is done. By using this date and the calibration interval, the next calibration date is calculated.

4. CASE STUDY AND RESULTS

The case study is aimed to show all the features of the implementation from the log in to the system and equipment registration to calibration schedule. All steps will be briefly described with screenshots of the system. A defibrillator with a brand name HP and model name Codemaster-XL will be introduced to the system for the Intensive Care Unit of the simulated healthcare unit.

4.1 Log – in

First, the user logs into the system. Biomedical and clinical engineers have the administrator access to the system.

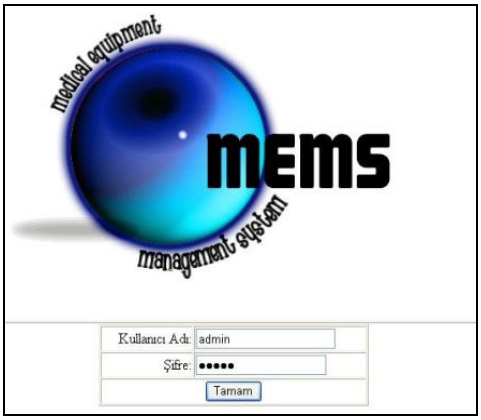


Figure 4.1 Log in page of MEMS

4.2 Medical Equipment Registration

The first part of the system is registering the medical equipment into the system. Biomedical engineer should check the existence of UMDNS code, model name and brand name of that kind of equipment in the system database.

From UMDNS reference list, UMDNS code for the defibrillator is found. It is 11129.

Figure 4.2 UMDNS reference list

In the Medical Equipment Registration part, defibrillator type is already registered. Therefore no type registration is necessary.

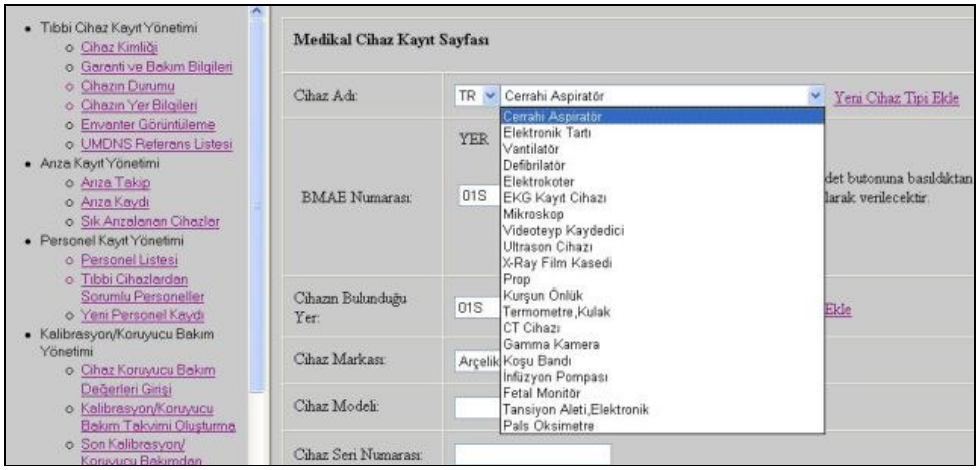


Figure 4.3 Medical Equipment Registration - Device Type

User will control brand name and model name. Brand name is also available in the database. He/she only needs to register the model name since it is not available.

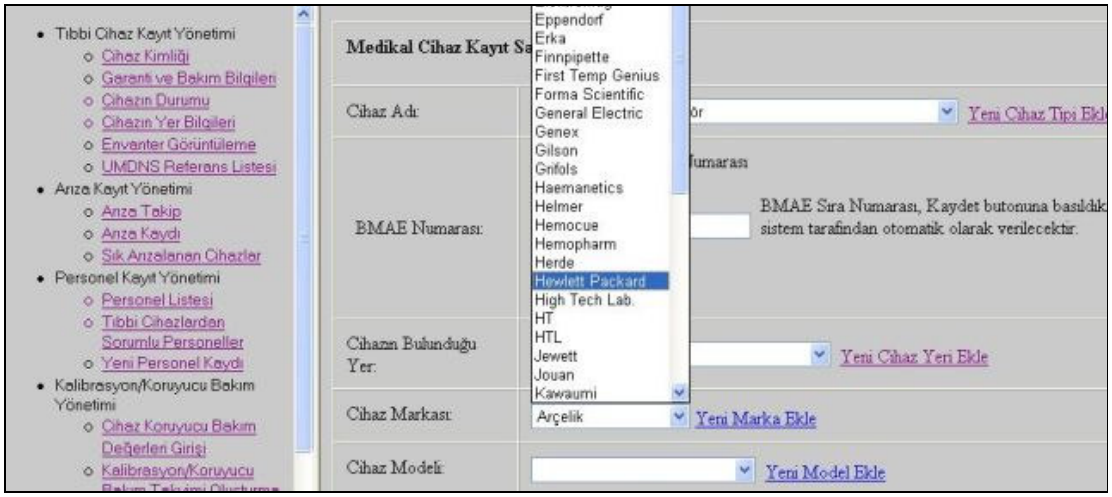


Figure 4.4 Medical Equipment Registration - Brand name

In the model registration part, model name and brand name of that model is entered and then Register button is pressed. Now, model name connected to the brand name is recorded to the system database. A warning message is appeared to indicate that the model name is recorded to the database.

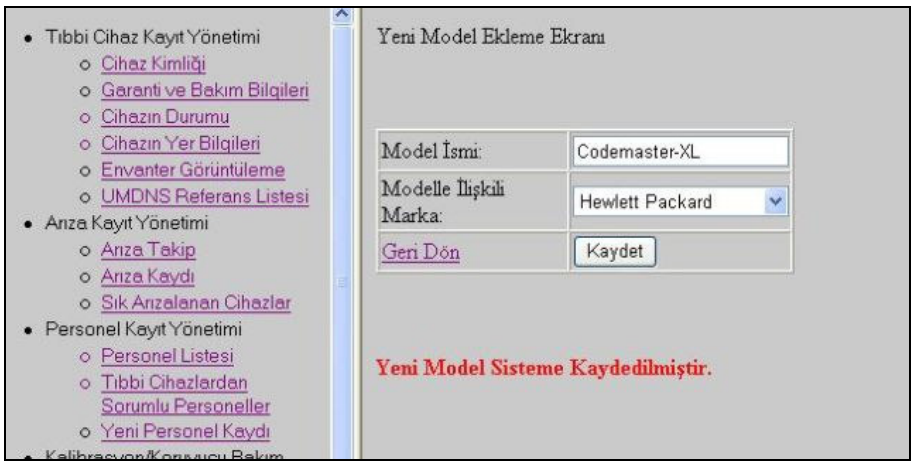


Figure 4.5 Medical Equipment Registration - Model name

To end with the registration procedure, other important parameters are entered in the registration page. Register button is clicked and warning message is seen showing that the device is registered with the Biomedical Inventory number of ACL11129001.

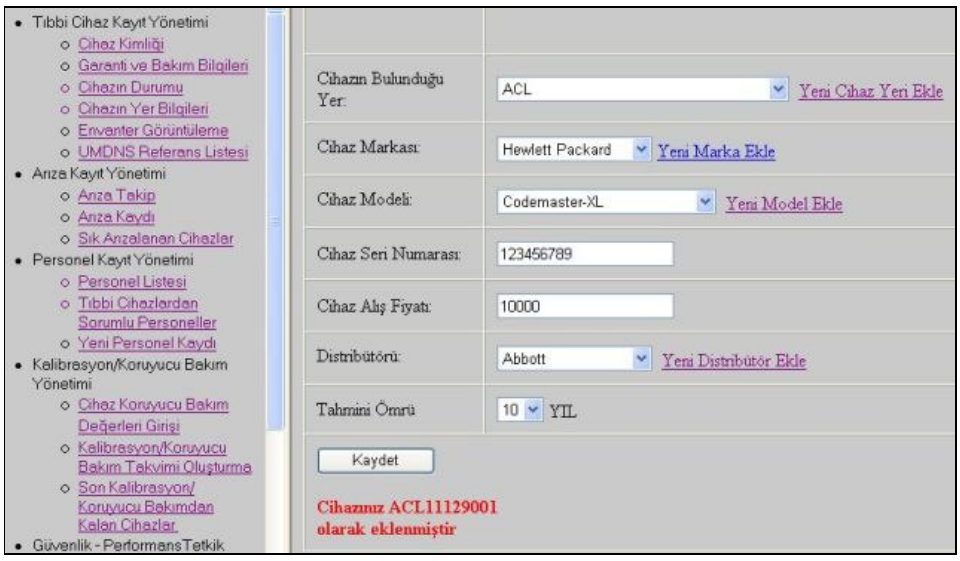


Figure 4.6 Medical Equipment Registration

4.3 Equipment Management Values

Since it is a brand new device, Equipment Management values for calibration and preventive maintenance should be controlled and if there is lack of information values should be entered.

Figure 4.7 Equipment Management Number Entry

If the user choose Defibrillator from the list and click “Search” button, available values are seen. User can change the values and then click “Record the Changes”. Users can use “Go Back” link to go to the main menu.

4.4 Warranty and Maintenance Information

Another part of medical equipment registration management section is warranty information of medical devices. Needed fields for warranty information of medical devices are given below.

Table 4.1

Warranty Information Table of Medical Equipment

Design Table 'GARANTI' in 'mems' on 'MASTERZ.COM'

	Column Name	Data Type	Length	Allow Nulls
▶	BMAE_ID	varchar	12	
	GARSURESI	varchar	10	✓
	SOZLESTARIHI	smalldatetime	4	✓
	SOZLESSURESI	varchar	10	✓
	SOZLESKAPSAM	varchar	20	✓
	BAKPERIYOT	varchar	10	✓
	UMDNS	varchar	5	✓
	SIRANO	varchar	3	✓

GARSURESI is the period of time that the warranty of the medical device is valid. SOZLESTARIHI is the date of agreement of warranty. SOZLESKAPSAM is the coverage of the agreement whether failed pieces of the equipment is included or not. BAKPERIYOT is the maintenance period of medical equipment in months.
Necessary fields about warranty information are entered to the system by using Warranty and Maintenance Information page.

Medical equipment warranty information is entered to the system from the related link. All necessary information is filled and then "Record" button is clicked. Warning message is appeared.

Figure 4.8 Warranty and Maintenance Information Entry

4.5 Medical Equipment Condition Entry

The present condition of the medical equipment is entered. It is entered as "Actively Used". This means that there is no failure condition and the device is working properly.
User can change this information whenever he/she wants.

Figure 4.9 Medical Equipment Present Condition

4.6 Equipment Acceptance Testing

For the new medical equipment, acceptance testing should be performed by biomedical engineering department. Therefore this information should be uploaded to the system like a list.

A new acceptance testing form should be prepared by the biomedical engineering department. After this form is prepared, it should be uploaded to the system.

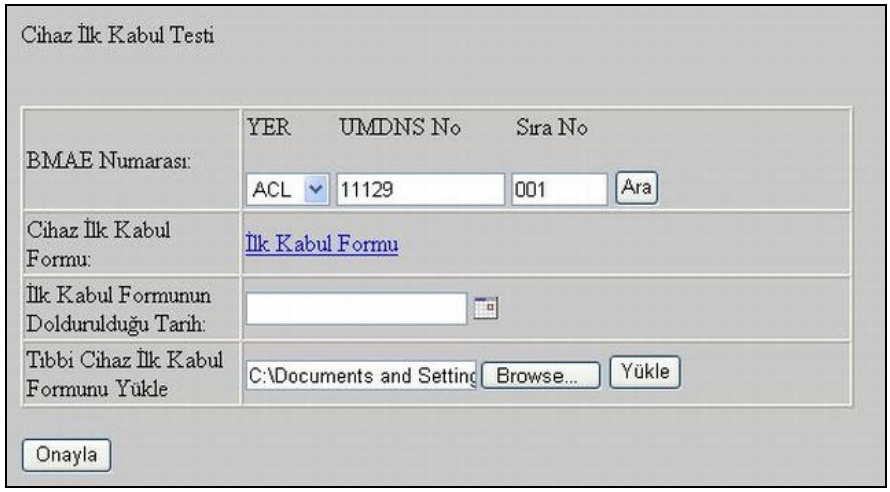


Figure 4.10 Acceptance Testing Form Upload

Acceptance testing form can be downloaded later on and filled by the biomedical engineering department. Filled form is again uploaded from this page, with the filled date of the form. The system overwrites the filled form on the blank acceptance form.

4.7 Failure Registration Management

Failure management, records all medical equipment failures, follow their repairing process and conclude and close their failure records. Failure management has very important role on statistical results. By using failure registration management, failure types, failure reasons can be identified. Also the devices that are most frequently failed can be listed.

Database table of Failure Registration Management is given below.
A failure identification number is assigned for all failure entries. FAILURE_ID is used for this reason. By using this number, users can follow a failure which is entered to the system whether it is resulted or not.

FAILURE_DATE is important to control the downtime analysis of medical equipment. Also this date is an indicator of time of repair for the evaluation of the technically responsible person, distributor, service or firm for equipment failures.

Table 4.2

Failure Entry Table of Failure Management

Design Table 'FAILURE_ENTRY' in 'mems' on 'MASTER'

	Column Name	Data Type	Length	Allow Nulls
▶	FAILURE_ID	varchar	11	
	FAILURE_DATE	smalldatetime	4	✓
	FAILURE_TURU	int	4	✓
	FAILURE_REASON	int	4	✓
	FAILURE_DEFINITION	varchar	50	✓
	ALARM_MESSAGES	varchar	50	✓
	MTarihi	datetime	8	✓
	Mkurum	varchar	50	✓
	Mudahaleci	varchar	50	✓
	Faaliyet	varchar	50	✓
	Sondurum	varchar	1	
	Maliyet	decimal	9	✓
	BMAE_ID	varchar	12	✓
	DTarihi	datetime	8	✓

FAILURE_TURU is the failure type of the medical equipment. There are various failure types depending on the equipment type. Mostly encountered failure types are listed

on the system as follows. Also new failure types can be added to this list by system administrator.

Table 4.3

Failure Types List of Failure Management

Data in Table 'FAILURE_TURLERI' i

ID	TUR
1	Elektrik Fişi
2	Elektrik Kablosu
3	Batarya/Akü Proble
4	Sigorta
5	Kayıt Mekanizması
6	Fan Bozukluğu
7	Kırık Cihaz Kutusu
8	Kırık Cihaz Sapı
9	Şebek Voltaj Hatası
10	Yazılım Hatası
11	Diğer
12	Bilinmiyor

Another analytic tool for failures is the failure reasons. Failure reasons are slightly differs from failure types. Failure reasons are the main reasons of failure. It can be an uneducated personnel use or improper use of medical equipment. Failure reasons are collected in another table under the name of FAILURE_REASONS. This table can also be expanded.

Failure reasons and failure types are list box typed information. User can select the appropriate failure reason and type from list box.

Table 4.4

Failure Reasons List of Failure Management

Data in Table 'FAILURE_REASONS'

ID	REASON
1	Eğitimsizlik
2	Yanlış Kullanım
3	Cihaz Yaşı
4	Kötü Kullanım

FAILURE_DEFINITION is used for detailed description of the failure written by responsible personnel. It is designed as an expandable text area for long descriptions. If there is an alarm message that the system gives, alarm messages can be entered to this

form. The user should select, “There is an alarm message” list item and then another text area appears on the screen for alarm message entry.

The last condition of the medical device is also important. User can select the appropriate last condition for the failed device.

Let’s create a failure entry for this equipment. Necessary information is filled by the biomedical engineering department.

Figure 4.11 Failure Registration Page

Failure reasons and failure types are entered. If there is an alarm message, “There is an alarm message” choice should be chosen. A blank text field will be automatically displayed. Failure description is filled. After approval of the failure registration, a failure registration number is given for this failure. This failure can be followed by this number from Failure Follow Up page.

4.8 Failure Follow-up Page

For the failure follow-up, failure registration number is entered to the system. When the “Search” button is clicked, failure information is shown. If the “List All” button is clicked, all registered failures can be listed.

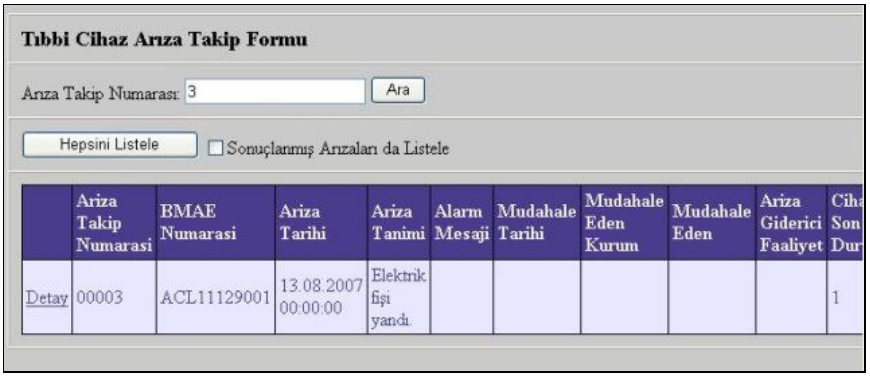


Figure 4.12 Failure Follow-Up Page

If the “Detail” link is clicked for this equipment, detailed information can be entered for the equipment. This information is very necessary for following all steps from failure registration to failure is finalized.

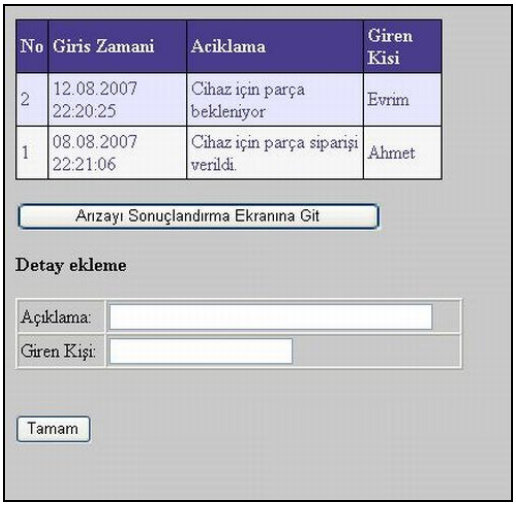


Figure 4.13 Failure Details for ACL11129001

4.9 Equipment Failure Finalization

For the failure finalization, there is a button “Finalize this Failure” button on the “Details” link. Failure finalization form is generated and filled by the user. A finalization warning message is shown in the page.

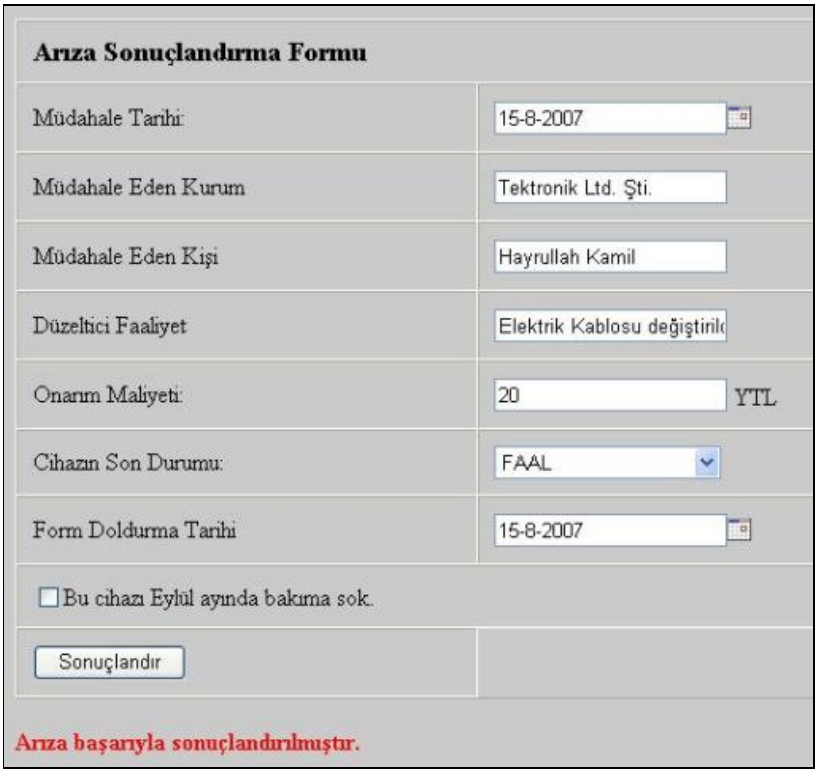


Figure 4.14 Failure finalization form**.**

4.10 Failure Frequency of Medical Devices

In this page, list of devices which have failure registration frequently are listed. Preventive maintenance and calibration frequency of the medical devices are shown in this list Biomedical engineers can see the frequency of failures and if they find it too much, maintenance and calibration frequency can be changed from this page.

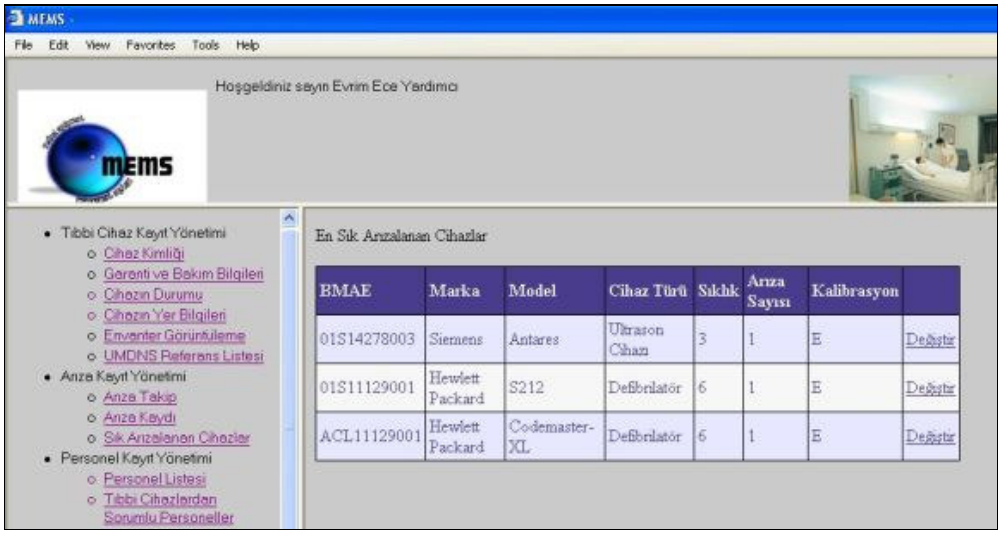
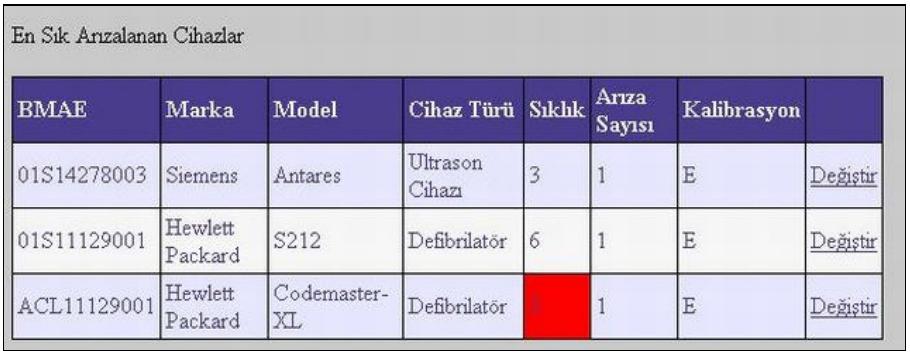


Figure 4.15 Failure frequencies of medical devices

Let's change the maintenance and calibration frequency of ACL11129001.
"Change" link is clicked for this equipment.

Figure 4.16 Failure frequency change for ACL11129001

On the new page, calibration frequency is changed from 6 months to 3 months and "Update" button is clicked. After clicking the button, user is redirected to another page that show the updated table of Failure frequencies. Updated field is shown with a red color.
If the user wants to change it again, the process is repeated or user can click on "Delete" button to change the frequency to the first frequency.


En Sık Arızalanan Cihazlar

BMAE	Marka	Model	Cihaz Türü	Sıklık	Arıza Sayısı	Kalibrasyon	
01S14278003	Siemens	Antares	Ultrason Cihazı	3	1	E	Değiştir
01S11129001	Hewlett Packard	S212	Defibrilatör	6	1	E	Değiştir
ACL11129001	Hewlett Packard	Codemaster-XL	Defibrilatör	3	1	E	Değiştir

Figure 4.17 Failure preventive maintenance and calibration frequency Update

If the maintenance and calibration frequency of a device is changed, this device is evaluated in a different manner in the preventive maintenance and calibration schedule. Other defibrillators on the list will be calibrated in every 6 months but this defibrillator is calibrated in every 3 months.

4.11 Personnel Registration and Management

Personnel Management tool is used to organize the personnel in charge of medical devices. Generally one or more personnel are in charge of protecting the medical equipment. Biomedical engineering department can register new personnel, see assigned personnel to specific medical equipment and list all responsible personnel on a specific department of the healthcare institute.

Sometimes it can be necessary to register new personnel to the system and assign a department to the personnel to be responsible of.

New personnel registration page is designed for this purpose. To register new personnel, clinical engineers should fill the form below with the name of the personnel, address and phone information for urgent cases, and the department that he/she is working. After pressing the Register button, all personnel information is registered the database for further use.

Figure 4.18 New Personnel Registration

Also personnel can be listed according to department that they are responsible for. If the users change the department ACL for intensive care unit, personnel on that floor can be listed.

Figure 4.19 Personnel List

4.12 Inventory Management

Users can see all inventory of the healthcare unit in the system.

In the inventory, biomedical inventory number, brand name, model name, distributor, cost of purchase, date of purchase and various important data are listed. Also some filters can e applied to the inventory. For example users can filter the inventory with a brand name or a model name. If the model name filter is used, only the devices with a given model name are listed.

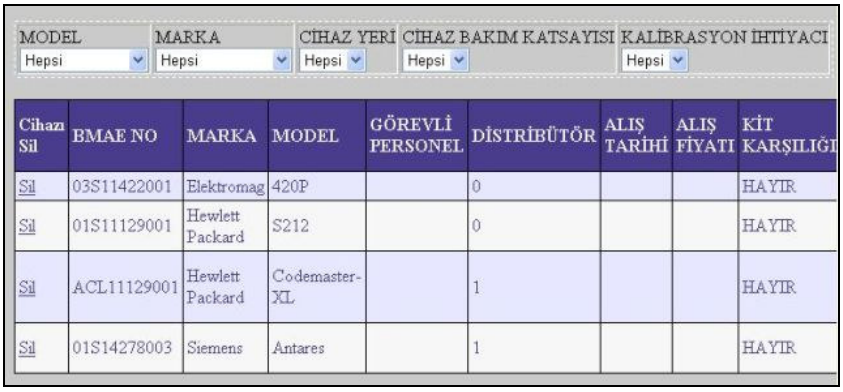


Figure 4.20 Inventory of the healthcare unit

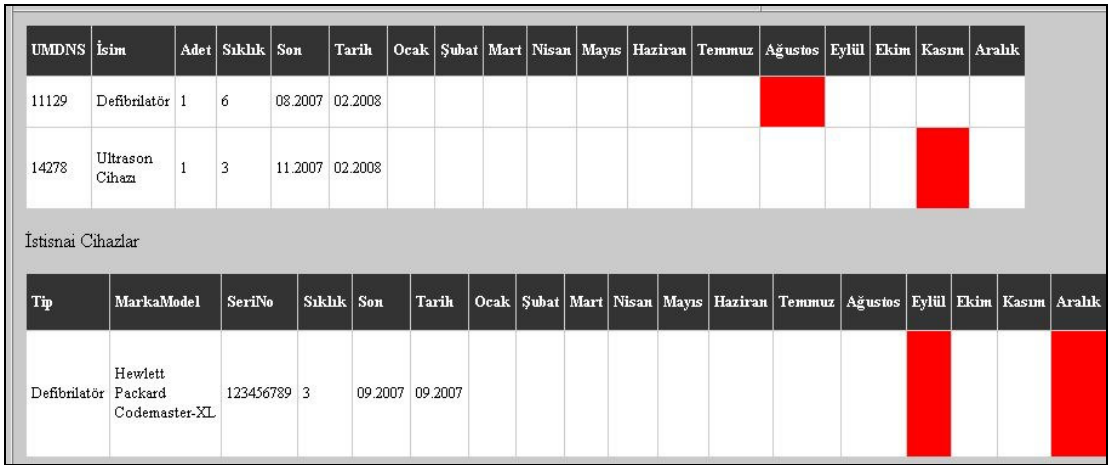
4.13 Preventive Maintenance and Calibration Management

Preventive Maintenance and calibration schedule is automatically created by the system. PM intervals are generated according to Equipment Management number. Generally intervals are 6 or 12 months. However, as it is showed before, it can be changed from "Frequency of Failures" page.

Figure 4.21 Preventive Maintenance and Calibration Schedule Main Page

Users can generate annually or monthly schedules. For the annual schedule, requested year is selected.

In the schedule, equipment groups are seen. The number of devices in the group is shown. The last calibration and PM month and also next calibration and PM month is given. PM intervals are given only by months and shown in red color. Maintenance date is up to biomedical engineer's choice.



UMDNS	İsim	Adet	Sıklık	Son	Tarih	Ocak	Şubat	Mart	Nisan	Mayıs	Haziran	Temmuz	Ağustos	Eylül	Ekim	Kasım	Aralık
11129	Defibrilatör	1	6	08.2007	02.2008												
14278	Ultrason Cihazı	1	3	11.2007	02.2008												

İstisnai Cihazlar

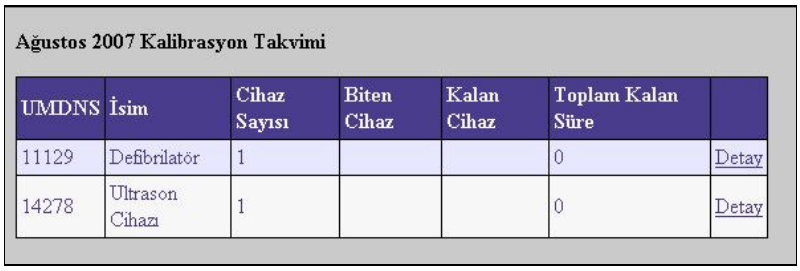
Tip	MarkaModel	SeriNo	Sıklık	Son	Tarih	Ocak	Şubat	Mart	Nisan	Mayıs	Haziran	Temmuz	Ağustos	Eylül	Ekim	Kasım	Aralık
Defibrilatör	Hewlett Packard Codemaster-XL	123456789	3	09.2007	09.2007												

Figure 4.22 Annual PM Schedule

It should be noted that, there is another list under the annual schedule and some medical devices are listed. If the PM interval of a medical device is changed by the user, this medical equipment is listed in another schedule called “Exception Devices”.

In the case study above, it is shown that, calibration interval of one of the defibrillators is changed by the biomedical engineering department from 6 months to 3 months. Therefore equipment with a Biomedical Inventory number ACL11129001 is separated from other defibrillators. It is an exceptional device in this case.

When the PM interval of this equipment is changed into its previous value, this exceptional defibrillator will be evaluated with other defibrillators.
For the monthly schedule, desired month is chosen from the list box. In the monthly schedule, medical devices inside a UMDNS group can be listed.



Ağustos 2007 Kalibrasyon Takvimi

UMDNS	İsim	Cihaz Sayısı	Biten Cihaz	Kalan Cihaz	Toplam Kalan Süre	
11129	Defibrilatör	1			0	Detay
14278	Ultrason Cihazı	1			0	Detay

Figure 4.23 Monthly PM Schedule

In this schedule biomedical engineers can see the details of the equipment group. Total calibration time, number of devices that are calibrated, number of devices that are not calibrated is listed. From the "Details" link, estimated calibration duration, total duration for the entire group of equipment can be seen. Calibration results can be added.

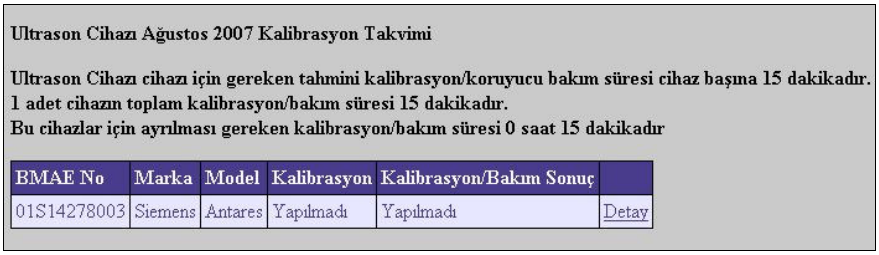


Figure 4.24 Monthly PM Schedule

If the user clicks "Details" button again, calibration results can be entered. PM/Calibration date and PM/calibration result is entered.

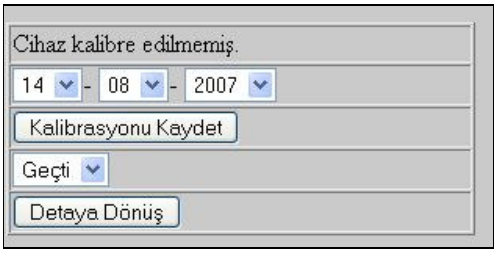


Figure 4.25 PM and Calibration Results

If the medical equipment is failed from the PM or calibration and if it is marked as "Failed" by the biomedical engineering department, this equipment is directed to the table "Devices Failed from the Last PM/Calibration Process".

Figure 4.26 Devices Failed from the Last PM/Calibration Process

This table only lists the devices that have a “Failed” information in their PM and Calibration result. It does not give any other information than the date of calibration. There are two different dates. One of them is the suggested PM/Calibration date and the other one is the date of PM/Calibration is exactly done.

4.14 Safety Performance and Inspection Management

Safety Performance and Inspection (SPI) Management is explained in detailed in the Literature Survey. It is a routine control for all medical assets of the healthcare unit. It is applied according to medical equipment producers and distributors.

A system is generated for this purpose. First of all biomedical engineering department should generate SPI forms for all medical devices according to producers advises.

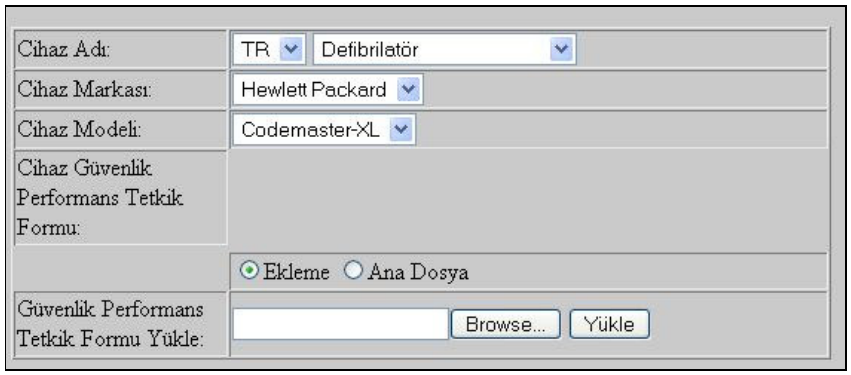


Figure 4.27 Safety Performance and Inspection Management Page

Generated blank form is uploaded to the system database. Main File radio button should be selected. Otherwise the system will not recognize the file as a blank SPI form. This blank form can be downloaded by the biomedical engineering department when a SPI is needed for the equipment. The file is filled and then re-uploaded to the system. The system automatically renames the uploaded file with the date of the day of upload. The system is capable of keeping hundreds of SPI forms for each device.

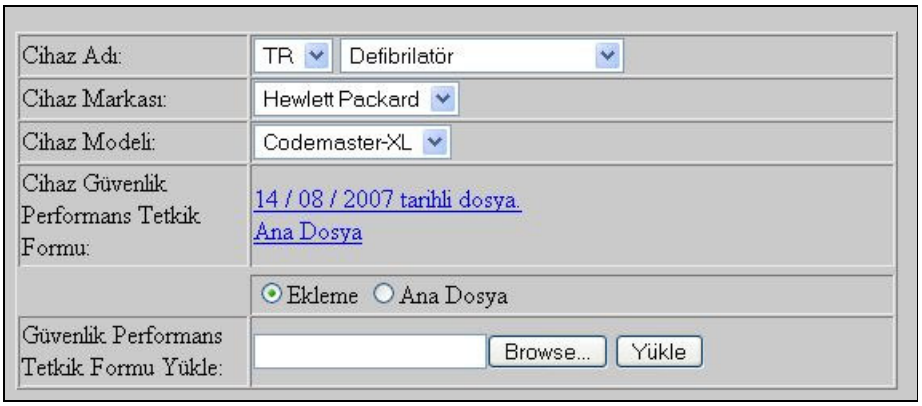


Figure 4.28 Safety Performance and Inspection - Forms Uploaded

4.15 Risk Scoring

For the risk scoring, a period of time should be passed after medical equipment is purchased. In that period of time, equipment failures and risks of injury that the equipment may take are observed.

Risk scoring is done by the biomedical engineering department. Necessary directions about risk scoring are given on the “Risk Scoring” page. For the equipment ACL11129001 risk scoring values are controlled. If the user click “Search” button, risk scores of that equipment is shown. If there is no risk scoring available for that device, a warning message is appeared to declare that there is no risk scoring values stored.

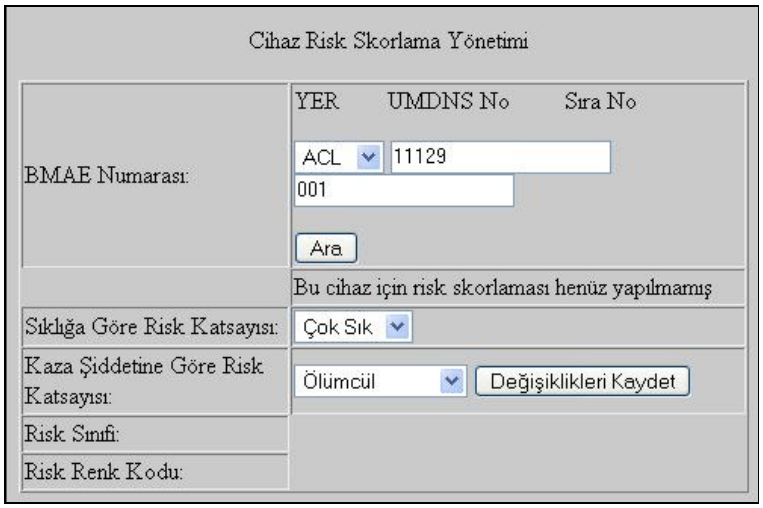


Figure 4.29 Risk Scoring Page before given the risk scores.

When the risk scoring is not available, user can directly enter the scores according to the directions.

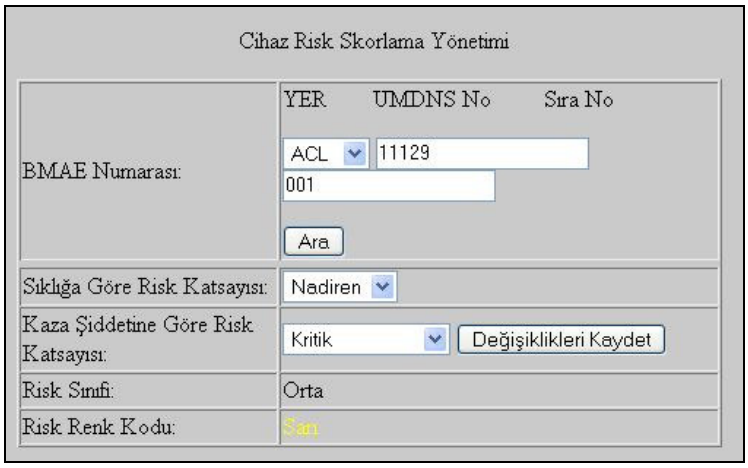
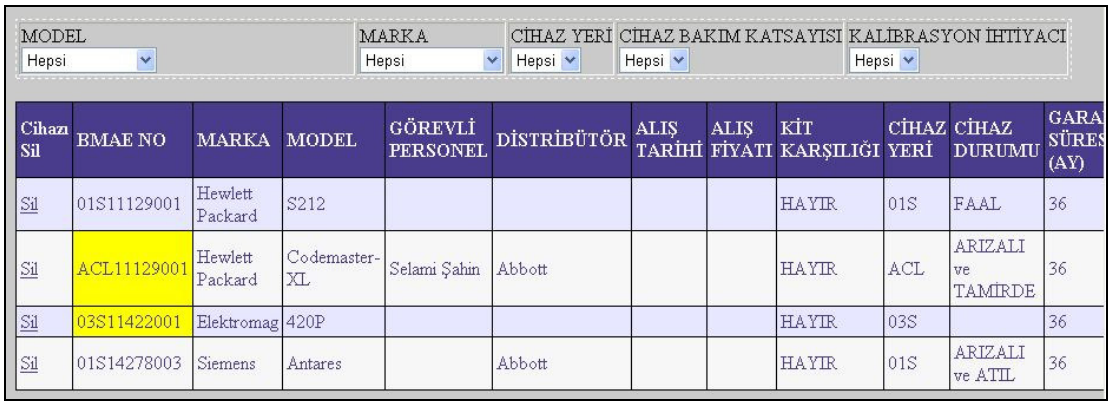


Figure 4.30 Risk Scoring after given the risk scores.

After given the scores for frequency of risk and severity of risk, risk classification of the medical equipment is automatically defined. Also a color code is given for the equipment. Color codes can be seen later from the Inventory.



MODEL: Hepsi	MARKA: Hepsi	CİHAZ YERİ: Hepsi	CİHAZ BAKIM KATSAYISI: Hepsi	KALİBRASYON İHTİYACI: Hepsi

Cihazı Sil	BMAE NO	MARKA	MODEL	GÖREVLİ PERSONEL	DİSTRİBÜTÖR	ALIŞ TARİHİ	ALIŞ FİYATI	KİT KARŞILIĞI	CİHAZ YERİ	CİHAZ DURUMU	GARA SÜRES (AY)
Sil	01S11129001	Hewlett Packard	S212					HAYIR	01S	FAAL	36
Sil	ACL11129001	Hewlett Packard	Codemaster-XL	Selami Şahin	Abbott			HAYIR	ACL	ARIZALI ve TAMİRDE	36
Sil	03S11422001	Elektromag	420P					HAYIR	03S		36
Sil	01S14278003	Siemens	Antares		Abbott			HAYIR	01S	ARIZALI ve ATIL	36

Figure 4.31 Inventory display with the color codes of risk classification.

4.16 Analysis and Graphical Representations

The most important benefit of using medical equipment management software is the statistical results obtained from collected information in the database. Statistical results are very valuable for decisions given about medical equipment by the clinical engineering department. If a device failed more than expected, biomedical engineers decide to discard that equipment and plan to buy a new one.

Since all the data about the inventory system is in hand, statistical results can be increased regarding to the needs of clinical engineering department.

Obtained statistical results are downtime analysis, repair cost factor analysis, and the results of the failure frequency by medical device type, medical device failures by hospital service and the failure reasons most frequently seen.

All statistical results are basically shown on a pie chart. To show the data on a pie chart, another plug-in is installed to the Visual Studio .Net environment used. This plug-in provides including two different kinds of information as x and y axis of the graph. The plug-in can also draw other types of graphs rather than pie charts.

4.16.1 Failure Frequency by Medical Equipment Type

In the failure registration part, all information about failed device is available. By using the UMDNS code of the failed medical equipment, failed devices are grouped. A pie chart is obtained from the installed plug-in with UMDNS codes versus number of failures. In Figure 4.32, obtained pie chart is shown. By analyzing this graph, biomedical engineer can easily understand which type of equipment is mostly fail.

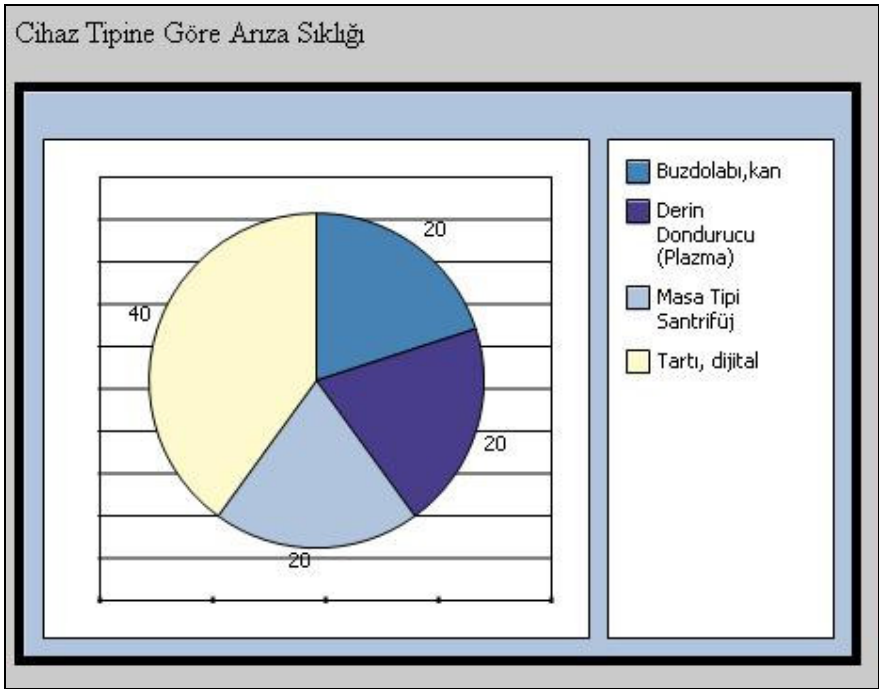


Figure 4.32 Failure frequency by medical equipment type.

4.16.2 Medical Equipment Failures by Hospital Service Type

This pie chart is again obtained from the failure registration information. The service that uses the failed equipment is also known. This time service versus medical equipment failed graph is drawn.

In Figure 4.33, it is seen that hospital service which has the most failure entry is plasma room. There are failure reasons stored in the database. Biomedical engineer should analyze that reasons and question why plasma room is the service that owns big portion of the failures. There can be an operator fault or the service has the most sensitive medical device or there is a medical device that is not possible to repair. In both cases, this information has a great importance for the biomedical engineering department.

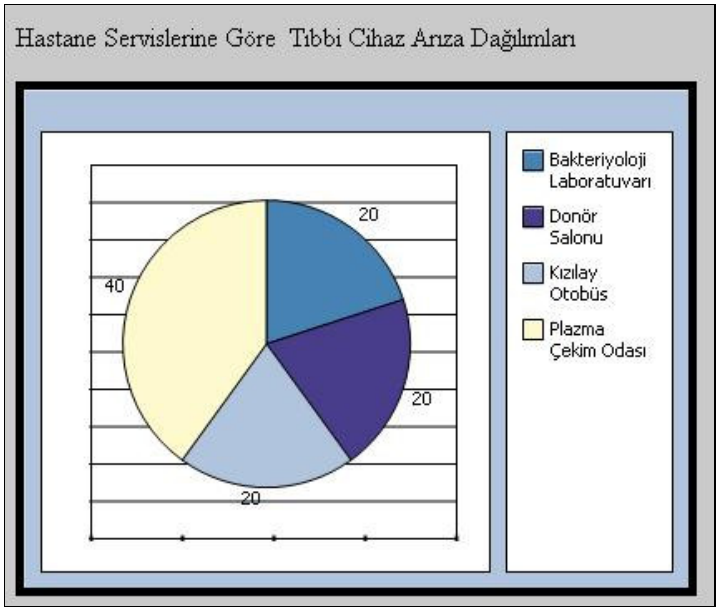


Figure 4.33 Medical Equipment Failure Rates

4.16.3 Frequently Seen Failure Reasons

Failure reasons are previously listed in the Failure Registration Management part. For the statistical information, failure entries recorded are grouped by their failure reasons. A pie chart is prepared failure reasons versus number of failures with that failure reason. Obtained pie chart is shown in Figure 4.34. According to the graph, 40% of the failures are seen because of the use of medical equipment by uneducated personnel.

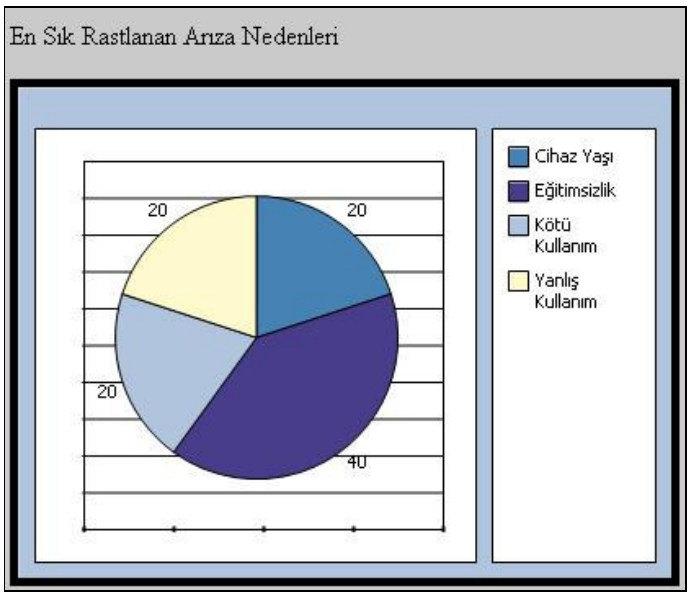


Figure 4.34 Failure Causes

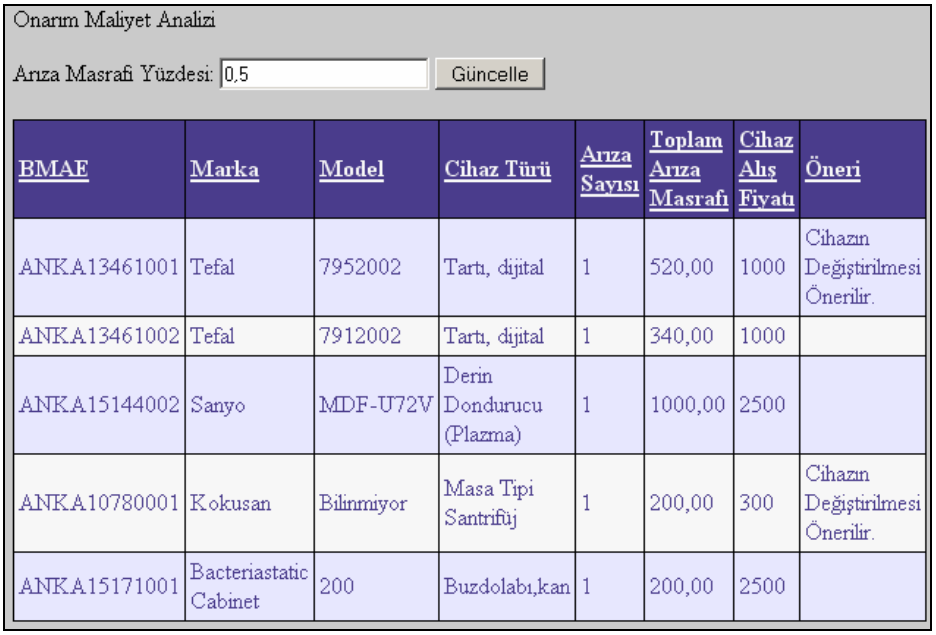
%20 is failed for the increased age of the medical equipment. %20 of them is failed because of the misuse of the medical equipment and %20 is failed because they are used very badly.

4.16.4 Repair Cost Factor Analysis

Repair Cost Factor is defined in the Theory part and formulized as

Repair Cost Factor = Cumulative cost of Repairs / Acquisition Cost

Cumulative cost of repairs is calculated by using the repair costs that are recorded to the system from Failure Result Form. Each time the medical equipment is repaired, the repair cost is entered. By simply adding up the cost of repairs, cumulative cost of repairs is obtained.


Onarım Maliyet Analizi

Arıza Masrafı Yüzdesi: 0,5 Güncelle

BMAE	Marka	Model	Cihaz Türü	Arıza Sayısı	Toplam Arıza Masrafı	Cihaz Alış Fiyatı	Öneri
ANKA13461001	Tefal	7952002	Tartı, dijital	1	520,00	1000	Cihazın Değiştirilmesi Önerilir.
ANKA13461002	Tefal	7912002	Tartı, dijital	1	340,00	1000	
ANKA15144002	Sanyo	MDF-U72V	Derin Dondurucu (Plazma)	1	1000,00	2500	
ANKA10780001	Kokusan	Bilinmiyor	Masa Tipi Santrifüj	1	200,00	300	Cihazın Değiştirilmesi Önerilir.
ANKA15171001	Bacteriastatic Cabinet	200	Buzdolabı,kan	1	200,00	2500	

Figure 4.35 Repair Cost Factor Analysis Page

Acquisition Cost is previously entered to the system when the equipment is first recorded to the system. Cumulative cost of repairs is divided by acquisition cost and Repair Cost Factor (RCF) is obtained. It is known that RCF is a coefficient between 0 and 2. This coefficient is entered at the top of the page by the system user as a cost percentage. If the RCF of a medical device is greater than the cost percentage entered by the system user, a replacement advice is appeared for that device.

For example the user enters RCF as 0,5. For the equipment with biomedical inventory number ANKA13461002, RCF is 340/1000. That is less than 0,5. Therefore there is no replacement advice seen. For the centrifuge, ANKA10780001 RCF is 200/300 which is greater than 0,5. Therefore a replacement advice is seen for that equipment. The user has the right of changing the RCF to be applied to the medical equipment by deleting the factor written on the textbox and changing it.

4.16.5 Downtime Analysis

In downtime analysis, the time passed from the failure entry to failure result is calculated. As it is said before, it is better to make the downtime shorter. Otherwise in every day the medical equipment is down, loss of healthcare unit is increased

For the calculation of downtime of a device, two parameters are used, the failure date of the medical equipment, and the day the equipment is repaired. When an equipment is repaired, system user is recorded the Failure Result Form. In that form there is a field called “Date of Repair”. In the Failure Entry Form failure date is also available. By subtracting failure date from date of repair, downtime is found.

Downtime of medical equipment is given in days not in hours. Example of a downtime analysis page is given in Figure 4.36. Other important parameters included are medical equipment inventory number, brand, model of the equipment, the person who deals with the repairing, number of failures that the equipment had and the equipment type. The other benefit of the downtime analysis page is that, when the equipment is failed more than once, downtimes of the equipment is automatically summed.

Atıl Süre Analizi

BMAE	Marka	Model	Atıl Süre (Gün)	Müdahaleci	Arıza Sayısı	Cihaz Tipi
ANKA15171001	Bacteriastatic Cabinet	200	46	biyomedikal	1	Buzdolabı,kan
ANKA10780001	Kokusan	Bilinmiyor			1	Masa Tipi Santrifüj
ANKA13461001	Tefal	7952002			1	Tartı, dijital
ANKA13461002	Tefal	7912002			1	Tartı, dijital
ANKA15144002	Sanyo	MDF-U72V			1	Derin Dondurucu (Plazma)

Figure 4.36 Downtime Analysis Page

4.17 Medical Equipment Replacement Management

For the management of medical equipment that has a replacement plan, a Replacement Evaluation Data Entry Page is designed. In this page, Biomedical Inventory number of selected medical device is entered by the user.

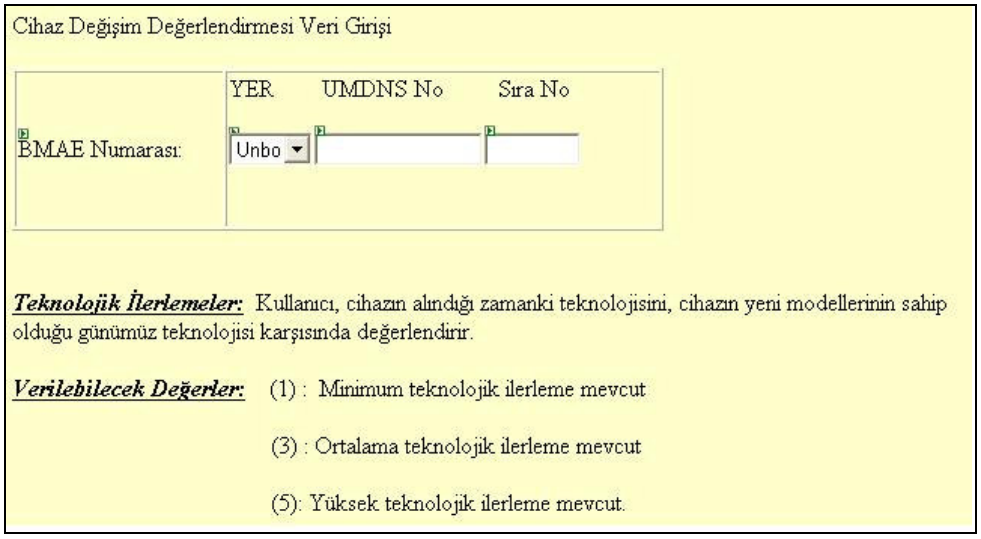


Figure 4.37 Replacement Evaluation Data Entry Page – 1

Small information about the evaluation of subjective factors is given in the page. These factors are Advancements in Technology and Fit into Five Year Plan. Users are informed about the evaluation procedure and values that can be given.

Users are evaluated the given subjective factors and approved the values by pressing the "Approve Data Entry" button.

Given values are recorded to the database for the calculation of Order Merit Number.

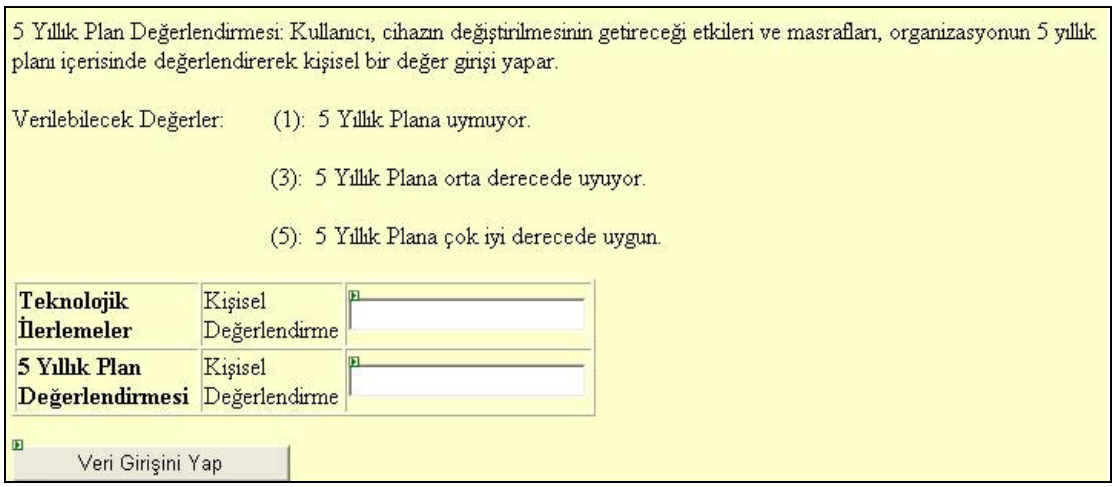


Figure 4.38 Replacement Evaluation Data Entry Page – 2

In the Medical Equipment Replacement Evaluation page, Biomedical Inventory Number is again entered by the user. This page is designed to show evaluated objective factors of the Replacement Management. User is pressed to the "Show Data" button.

Figure 4.39 Medical Equipment Replacement Evaluation Page

After pressing the button, all other elements of the evaluation factors are filled to the Analysis table such as age, number of workorders, expected lifetime, cost of repairs and equipment cost. Weights are given as default values however user can modify the weights. Calculated values of the Evaluation Factors are shown. Also subjective factors that are taken from the user on the previous step is listed.

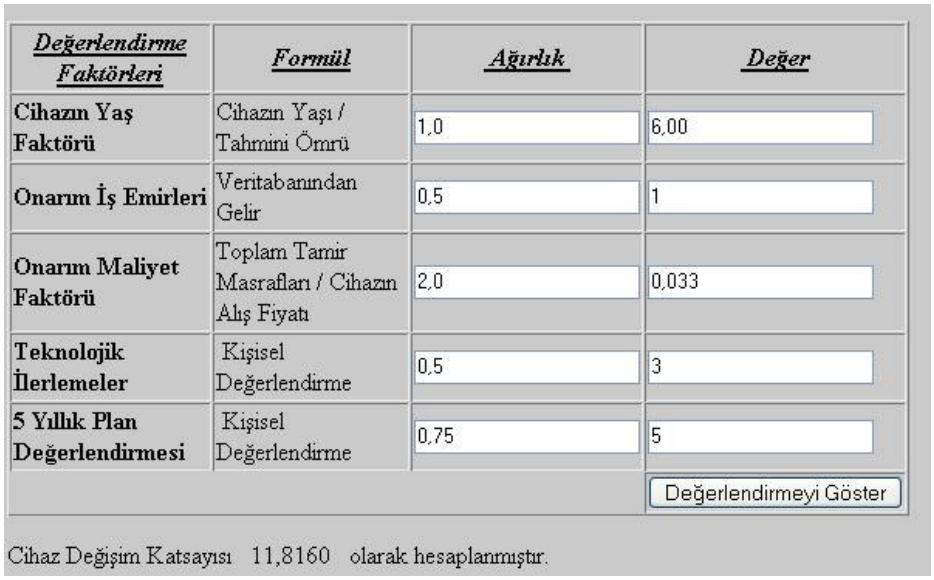


Figure 4.40 Medical Equipment Replacement Management Evaluation Table

The user is pressed the "Show Evaluation Button". Order Merit Number is calculated immediately for that equipment.

To see the list of all medical devices according to their Order Merit Number, another page is designed. In this table, medical devices that have previously entered evaluation factors in the registration pages and evaluation data entry pages are listed.
In this page medical devices are listed in ascending order by Order Merit Number. Other listed columns are Biomedical Inventory number, Equipment Name, Model, Brand, Serial number, Acquisition date, Expected lifetime, number of Repair Workorders and Acquisition price

BMAE Numarası	Cihaz Tipi	Üretici	Model	Seri #	Alış Tarihi	Tahmini Ömür	Onarım İş Emri	Toplam Onarım Maliyeti	Alış Fiyatı	Teknolojideki İlerlemeler	5 Yıllık Plana Uygunluk	Cihaz Değişim Katsayı
01S10217001	Cerrahi Aspiratör	Helmer	PFS 48	53838228	01-01-2001	10	1	3000,00	23000			
01S11129001	Defibrilatör	Hewlett Packard	S212	776655456	01-01-2001	5	1	1450,00	40000			
ACL11129001	Defibrilatör	Hewlett Packard	Codemaster-XL	123456789	01-01-2001	10	1	5000,00	70000			
01S11129003	Defibrilatör	Finnpipette	10-100µl	47473	01-01-2001	10	0	0	55000			
03S11422001	Elektrokoter	Elektromag	420P	435733542	15-01-2001	3	0	0	500000	5	5	8,25000
01S14278003	Ultrason Cihazı	Siemens	Antares	342342341	01-01-2001	1	1	1000,00	30000	3	5	11,8166

Figure 4.41 Medical Equipment Replacement Table

5. DISCUSSION AND RECOMMENDATIONS

This study aimed to design a web based system about medical equipment management to support the preventive maintenance, calibration, inventory control and failure control of a healthcare organization and to give recommendations for decreasing possible problems in planning, design and implementation phases of the study.

The results of this study showed out that the potential difficulties were related to the cost of a system, standardization of related data, security of the system, exception handling, implementation difficulties and finishing the system on-time and on-budget. Implementation difficulties were not about of the major implementation problems related to software, hardware, algorithm or major security problems but it is related to the adapting the existing system of the healthcare unit to the new system.

End users of the system were another reason of implementation difficulties. It was very hard to change their existing system and convince the end users to use the new system. Since general computer skills, clinical system experience and computer usage tendency of end users were not sufficient, user training became an important issue. It could not be supported from a long distance. However, since the system was very user friendly, there was not any problem about the system use of the related healthcare personnel. In the future, user trainings can be recommended for the professional use of the system.

Furthermore, there were lots of benefits that the medical equipment management system brings. The advantages of the implementation were related to reducing the clinical errors, increasing the overall quality of biomedical engineering department and hospital medical equipment infrastructure and also decreasing the dependency on personnel in charge of medical equipment management.

It is very important to make a system easy to modify. Modifications are often necessary for the system upgrades. The system should be designed in a way that it will be immediately changed and prepared for the use of another hospital. In this system, this

modification facility was not considered seriously at the beginning of the studies. Therefore when inventory change was needed, it became a very difficult task to change the all hospital dependent parameters.

User - programmer interaction had a great role on increasing the usefulness of the system. In some stages of the coding, there were mistakes done because of the lack of communication between the end users and the system administrator. This resulted with time and performance consumption. Because of that reason, it is recommended to continue the software programmer and end user communication at maximum level.

The system was planned as a web based system. The reason of choosing a web based system was that, a web based system is accessible every time and every where. All users can easily log in to the system and used the system from any computer connected to the Internet.

For the preventive maintenance and calibration procedures, preparing a schedule was a problem in previous methods and programs used. Automatic schedule preparation was a kind of innovation in the preventive maintenance of medical equipment. However lots of information was needed before the automatic schedule preparation. The first one was the inventory. Devices were observed and included to the PM program regarding to the medical equipment inclusion criteria suggested by Fennigkoh [14].
Codes were generated to obtain PM schedules and statistical information and graph generations.

After all system was finished and became practicable, testing was started. First system tests were done, bugs, nonworking links, wrong codes were repaired. Page design was changed.

Secondly, system tests and system simulations were started. The suggested system is tested in a healthcare institute for three months. In this time, communication with the department was provided for every problem encountered. There were not huge mistakes in the system. There were small errors on the system like improper design and nonworking links. These errors were found in the user test by the biomedical engineering department. Also some ideas from the department were taken into account and system was revised. Testing phase was really useful for future developments of the software.

Taking the literature survey and the findings of this study into consideration, the followings can be recommended for achieving a successful, sufficient and efficient medical equipment management software implementation:

- The web interface of the system is the most important thing for the end users. Consideration of the user interface should be one of the main issues. The system must be as user friendly as possible.
- User – system programmer relation should be seriously taken into account. Generally, user wants and programmer's offers do not meet. To find a common point, exchange of ideas and brain storming is necessary.
- Healthcare personnel who are the system users should express their expectations from the designed system clearly. Unnecessary or impracticable requests will be time consuming.
- System users should prepare necessary data before the system design is started. Proper inventory preparation, medical equipment information such as brand name, model, serial number, calibration and preventive maintenance information, distributor or related firm information should be provided in advance.

In order to solve the implementation difficulties and recommend new solutions, system can be revised, developed and similar test studies can be done in university and public hospitals. It is hoped that, this system is going to achieve the expected benefits for medical equipment management, inventory management and preventive maintenance and calibration planning.

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