MEDEMAS - MEDICAL DEVICE MAINTENANCE MANAGEMENT SYSTEM via REMOTE ACCESS

by

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ABSTRACT

MEDEMAS - MEDICAL DEVICE MAINTENANCE MANAGEMENT SYSTEM via REMOTE ACCESS

As the technology improves rapidly, diagnosis and treatment devices that directly affect human health increase in number and variety. Unfortunately, these devices carry their own risks. Any hazardous/defective device can harm user or patience; or mis-calibrated devices can give birth to wrong diagnosis and treatment. Thus, medical devices' proper selection, planned and in time periodic maintenance, repair and calibration processes become more of an issue.

The aim of the study was to develop a medical device maintenance management software which would keep inventory of medical devices; their maintenance procedures and repair/maintenance histories; and would automate maintenance scheduling process, using the proper algorithm for maximum efficiency. Another aim was to make it possible to carry out and complete the maintenance process remotely, making use of proper maintenance procedures.

In the proposed study, a medical device maintenance management system, MEDEMAS was designed and implemented which provides a data pool of medical devices, maintenance procedures and related information. The system also contains repair and maintenance history of devices. MEDEMAS creates optimal maintenance schedule for devices and enables to carry out and report maintenance processes via remote access. The study aims to make the maintenance process more accurate, efficient, faster and easier to manage and organize; and much less confusing. Accumulated history of the devices and personnel helps in risk management and replacement planning.

Keywords: Medical Device, Medical Device Maintenance, Calibration, Maintenance Procedure, Scheduling, Remote Access.

ÖZET

MEDEMAS - UZAKTAN ERİŞİMLE TIBBİ CİHAZ BAKIM YÖNETİM SİSTEMİ

Başdöndürücü bir hızla gelişen teknolojiyle birlikte doğrudan insan sağlığını ilgilendiren teşhis ve tedavi cihazlarının miktarı ve önemi artmaktadır. Ancak, her cihaz birtakım riskler taşır. Hatalı/arızalı cihazlar hasta ya da kullanıcıya zarar verebilir; ya da yanlış kalibre edilmiş cihazlar hatalı teşhis ve tedaviye sebebiyet verebilir. Bu yüzden, bu cihazların doğru seçimi; bakım - onarım, test ve kalibrasyonlarının en iyi şekilde planlanıp bu doğrultuda yürütülmesi ve kayıt altına alınması ön plana çıkmıştır.

Bu çalışmanın amacı, tıbbi cihazların, bakım prosedürlerinin ve bakımla ilgili diğer verilerin envanteri ile arıza ve bakım/kalibrasyon geçmişlerinin tutulduğu; en etkin bakım takvimi otomatik olarak oluşturabilen bir tıbbi cihaz bakım yönetim sistemi oluşturmaktır. Tıbbi cihaz bakımını, kaydedilen prosedürleri kullanarak uzaktan erişimle yapılabilir hale getirmek diğer bir hedeftir.

Sunulan çalışmada bir tıbbi cihaz envanter yönetim sistemi (MEDEMAS) tasarlanmış ve programlanmıştır. Sistem, tıbbi cihaz bilgileri, bakım prosedürleri ve ilintili bilgilerden oluşan bir veri havuzuna sahiptir. Cihazların arıza, bakım ve kalibrasyon geçmiş verileri de tutulur. MEDEMAS, cihaz için uygun bakım takvimini otomatik olarak oluşturur, ve bakım/kalibrasyon işleminin uzaktan erişimle yapılmasını ve bilgilerin sisteme hemen aktarılmasını sağlar. Çalışmanın hedefi bakım/kalibrasyon işlemini daha doğru, etkin, hızlı ve kolay yönetilir ve çok daha az karmaşık hale getirmektir. Cihaz ve personel geçmiş bilgisi risk yönetimi ve değişim planlamasında yardımcı olur.

Anahtar Sözcükler: Tıbbi Cihaz, Tıbbi Cihaz Bakımı, Kalibrasyon, Bakım Prosedürleri, Takvim, Uzaktan Erişim.

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LIST OF ABBREVIATIONS

MEDEMAS	Medical Device Maintenance Management System
GHTF	Global Harmonization Task Force
JCI	Joint Commission International
ISO	International Organization for Standardization
ISM	Integrated Service Management
GE	General Electric
ECRI	Emergency Care Research Institute
IPM	Inspection and Preventive Maintenance
ECG	Electrocardiography
AAMI	Association for the Advancement of Medical Instrumentation
UMDNS	Universal Medical Device Nomenclature System
AE	Adverse Event
NRL	Natural Rubber Latex
PDA	Personal Digital Assistant
GPRS	General Packet Radio Service
HTML	HyperText Markup Language
SMS	Short Message Service
IT	Information Technologies

1. INTRODUCTION

The role of medical devices in healthcare is essential. The Global Harmonization Task Force has proposed the following harmonized definition for medical devices (GHTF document SG1/N029R11) [1]:

"Medical device" means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury
- investigation, replacement, modification, or support of the anatomy or of a physiological process
- supporting or sustaining life
- control of conception
- disinfection of medical devices
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

As the technology improves rapidly, diagnosis and treatment devices that directly affect human health increase in number and in variety. Unfortunately, these devices carry their own risks. Gradual equipment deterioration without maintenance may bring the safety level below an acceptable level of manageable risk. Any defective device can

harm user or patience; or mis-calibrated devices can give birth to wrong diagnosis and wrong treatment. Thus, those medical devices' proper selection, planned and in time and periodic maintenance, repair and calibration processes come into prominence.

WHO states that it is estimated that around 50 percent of medical equipment in developing countries is not functioning, not used correctly, and invariably not maintained, with serious consequences for patient care. This may be because the equipment was not needed or not appropriate, and most often lies idle for want of a spare part. It is critical, therefore, that a medical device management policy exists that includes a financial provision for maintenance, spare parts and training in the initial cost of the equipment [2].

It is critically important that the safety and performance of medical devices are continually assessed when they are in use, as these characteristics can only be proven if one measures how a device stands up in these conditions. No amount of rigour in the pre-marketing review process can predict all possible device failures or incidents arising from device misuse. It is through actual use that unforeseen problems related to safety and performance can occur [1].

Joint Commission International Accreditation sets the standard for medical equipment and utility systems as: The organization plans and implements a program for inspecting, testing and maintaining medical equipment and documenting results [3]. Keeping medical devices safe and effective will require planned preventative maintenance and breakdown maintenance carried out by competent people. In addition it is a legal requirement of the trust to ensure that equipment used by patients and staff is safe, and to this end appropriate maintenance regimes are both necessary and statutory.

With contributions of diversity and innovativeness of medical sector, especially in last years, the sector's quality understanding and expectations expanded. Reliability, safety and successful risk management rose out, bringing along hospital accreditation.

Accreditation has been defined as [4] "A self-assessment and external peer assessment process used by healthcare organizations to accurately assess their level of performance in relation to established standards and to implement ways to continuously improve". Accreditation provides a competitive advantage in the health, improves risk management and risk reduction and helps organize and strengthen patient safety efforts. Thus it leads to a severity in medical device maintenance, urging the need for a regular maintenance system.

Each device type has its own maintenance procedure, determined by international commissions like ISO and ECRI; however all procedures are not commonly shaped and classified in terms of computing. Classifying and standardizing procedures will make it possible to transfer them to computer environment; and by designing a proper algorithm, it will be possible to implement a management system for medical devices. This will basically include maintenance, repair and calibration of devices and maintenance scheduling.

MEDEMAS design shapes medical device type, medical device, procedure definitions and maintenance process itself. One component of the system is a database management application that gathers all parametric data from user (definitions). Second component is medical device maintenance application that administers device failure, repair, calibration and maintenance processes. This application is a mobile web application to let users easily use it in location of medical devices.

There is a powerful reporting facility of MEDEMAS which can be used by administrators only. Reports are up to date as they are dynamically created. They are informative and helpful in decision making as they are statistical reports.

Management appointments are created automatically, taking into consideration medical device, measurement device and technical staff resources.

There is also a tiny but efficient information system that regularly sends informative and reminder e-mails to technical and administrative staff about maintenance

appointments.

MEDEMAS tidies up medical device - maintenance - procedures complex in the simplest way for the user. It leads the user for the maintenance and creates the maintenance schedule instead of him/her.

MEDEMAS will increase patient and user safety, will increase medical devices' performance and efficiency, will lengthen medical device life, will prevent possible failures, will decrease repair and investment expenses, and will satisfy accreditation expectations. Naturally, patient and employee satisfaction will be increased as a result.

Chapter 2 presents origin of the problem and puts forward the organizations that state medical device maintenance requirements. Previous computational approaches to solution and organizations' work on procedures, coding systems and other classifications are also presented in this chapter.

In Chapter 3, our problem analysis and solution offer is detailed. Design considerations and detailed system architecture can also be found here.

Chapter 4 includes our study results. Since the study is a software application, results explained are application pieces, supported with design details and application screenshots.

Chapter 5 contains a short conclusion and gives hint of future scope.

2. BACKGROUND

Medical Devices in hospitals must be regularly maintained to ensure safety and reliability; and prevent failures. Device Maintenance is not a random process; each device must ensure certain standards and there must be device type specific maintenance procedures previously defined. World Health Organization (WHO) states that standards are essential as they:

1. Provide reference criteria that a product, process or service must meet.
2. Provide information that enhances safety, reliability and performance of products, processes and services.
3. Assure consumers about reliability or other characteristics of goods or services provided in the marketplace.
4. Give consumers more choice by allowing one firm's products to be substituted for, or combined with, those of another [1].

There are organizations that establish such international requirements, standards and procedures. Joint Commission and ISO standards are the most eligible organizations that provide medical device maintenance requirements.

2.1 Joint Commission International (JCI) Requirements

JCI is an independent, not-for-profit organization that accredits and certifies international healthcare organizations and programs.

Accreditation and/or Certification is a process in which an entity, separate and distinct from the healthcare organization, usually non-governmental, assesses the

healthcare organization to determine if it meets a set of standards requirements designed to improve quality of care. This voluntary process provides a visible commitment by an organization to continually ensure a safe environment for its patients and staff.

JCI develops standards and requirements to be fulfilled for accreditation; including medical device regulations. Standard EC.6.10 [5] requires the hospital to establish a current, precise, and unique inventory of all medical equipment managed under the medical equipment program. The medical equipment inventory should not be restricted to devices included in the medical equipment maintenance program. An accurate and complete inventory is critical for various medical equipment management functions, including tracking of manufacturers' recalls, documenting the cost of maintenance, replacement planning, scheduling maintenance work, and tracking model-specific and device-specific issues. It claims that it is desirable to keep the medical equipment inventory highly accurate, and random samples should be taken periodically to assess the inventory's accuracy. One method could be to document monthly the number of items that could not be located that are on a monthly preventive maintenance (PM) schedule. The hospital is also required to test all medical equipment for safety and performance before it is initially used in the hospital.

2.2 International Organization for Standardization(ISO) Requirements

ISO defines itself as the world's largest developer and publisher of International Standards. It is a network of the national standards institutes of 161 countries, one member per country.

ISO publishes international standards for medical device requirements; standards are not cumulative, each device type has its own standard(s). These standards claim to guide device production, test, installation and post-installation maintenance processes. A fragment of ISO standard for anaesthetic ventilators (ISO 8835-5:2004)

is included here, further information can be found on standard document [6].

51.101 Operator-adjustable pressure limitation

The **anaesthetic ventilator** shall be equipped with an **operator**-adjustable means to limit the pressure applied to the **anaesthetic breathing system.** The means of limitation shall ensure that the airway pressure does not deviate from the set value by more than $\pm kPa(10cmH_2O)$ or 15 percent of the set value, whichever is the greater.

NOTE $*$ Because of the differing ways in which pressure limitation may be used in clinical practice, this device standard does not specify the relationship between the means of **operator**-adjustable pressure limitation and the pressure alarm system.

51.102 Failure-to-cycle alarm

If the anaesthetic ventilator is provided with a "failure-to-cycle" **alarm system**, the **alarm signal** shall be at least a medium priority.

51.103 Operator-adjustable pressure alarm

51.103.1 The **anaesthetic ventilator** shall be equipped with an **operator**-adjustable **alarm system** to indicate when the pressure in the **anaesthetic breathing system** has exceeded a set limit. This **alarm signal** shall be at least a medium priority **alarm signal**.

51.103.2 If the **anaesthetic ventilator** is equipped with a means to annunciate an **alarm signal** following failure of the pressure to reach the operator-set minimum pressure threshold, the **alarm signal** shall be at least a medium priority.

2.3 Previous Work

It has been reported in the literature that successful applications of various maintenance optimization models, including inspection models, are rare. The major problems in applying the models are:

- computational difficulties;
- difficulties of collection of data and modeling of failure distribution; and
- the gap between theory and practice [7].

2.3.1 Software Applications

i. Siemens Integrated Service Management^{TM} (ISM)

Siemens Integrated Service Management^{TM} offers a single-source solution for all medical-equipment-related service and maintenance needs, even for third-party devices. This frees the staff from time-consuming administrative responsibilities, enables the implementation of advanced proactive services throughout the hospital, and allows the customers to focus on their core competencies [8].

It is "a package that covers the analysis, planning, management and monitoring of all of your medical- systems-related service and maintenance activities. It also ensures compliance with legal standards and industry regulatory guidelines" [8].

This product is rather an assistant tool administered by an ISM site manager and any hospital requirement (like reporting) is forwarded to Siemens/ISM manager. An in-depth direct access is not available; and the product is not intended for maintenance management by hospital personnel.

ii. SAP

SAP is a German software development and consulting corporation, which provides enterprise software applications and support to businesses of all sizes globally. SAP is an expert company in database management and workflow applications.

SAP for Healthcare integrates healthcare processes and provides an end-to-end solution for all administrative and clinical processes. SAP for Healthcare includes sub-modules that keep inventory of medical devices and administer service data [9]. However, there is no medical device maintenance module implemented on SAP for Healthcare.

iii. AssetPlus^{TM} by GE Healthcare

GE Healthcare is a sub unit of General Electric (GE). It has many products/services among which exist medical imaging and information technologies to medical diagnostics, patient monitoring systems, drug discovery, and biopharmaceutical manufacturing technologies. Further information can be found on GE Healthcare web site [10].

AssetPlus^{TM} is the product of GE that is for tracking equipment and instruments. GE identifies AssetPlus^{TM} as "A benchmark tool for tracking the essential maintenance and investments which keep healthcare institutions running smoothly. Having kept pace with regulatory changes, AssetPlus^{TM} meets the very latest traceability and productivity demands. Ultimately AssetPlus^{TM} tracks the full life-cycle of each and every asset, zooming in to identify, analyse and correct any equipment malfunctions" [11].

Asset Plus keeps device inventory; and a history of all requests for repairs, servicing, as well as investment and renewal. Its target is "to become the essential answer to traceability management needs while at the same time expediting accurate record-keeping" [10].

This product does not handle maintenance itself, accepts maintenance as outsourced and it rather tracks maintenance results and history. Other facilities like inventory, maintenance and failure history and analyzes comply with our study.

iv. BioPro

BioPro is the product of a native company, Davon Information Technologies. It is a maintenance management system that is prepared for healthcare sector using Web 2.0 technologies [12]. BioPro supports tracking inventory and processes, and

analyzing data for decision making. Though it makes it possible to follow and report maintenances, again this product does not guide maintenance. We had the chance to try this product, and saw that it is rather a medical device management and workflow application.

v. ECRI-AIMS^{TM} Equipment Management System

ECRI-AIMS^{TM} is a new system for managing all aspects of technology-based assets found in European and International healthcare institutions. It is a web-browser application, enabling the data stored centrally by the hospital to be accessed simply via a web-browser connected to the hospital intranet [13].

The system provides a complete resource for managing equipment inventory information, work orders, service contracts, spare parts, purchasing and stock-control in a single, secure, comprehensive yet easy-to-use package.

2.3.2 Maintenance Procedures: ECRI

ECRI Institute, a nonprofit organization, has been dedicated to bringing the discipline of applied scientific research to discover which medical procedures, devices, drugs, and processes are best, all to improve patient care.

ECRI Institute publishes hazard reports and alerts on medical devices, hospital adverse event and near miss reports, health technology journals, directories for medical device manufacturers/suppliers, healthcare-related standards, clinical evidence and emerging technology analyses and systematic reviews.

ECRI Institute's Health Devices Inspection and Preventive Maintenance (IPM) System [14] provides a database of ECRI Institute-developed IPM procedures and forms for commonly inspected devices and systems like anaesthesia units, infusion pumps, and

ventilators. ECRI Institute's procedures derive from health devices evaluations and hazard reports as well as from ECRI Institute's accident investigations. This means that ECRI Institute's procedures are based on clinically significant considerations, not just on manufacturers' recommendations.

A piece of Defibrillator Maintenance Procedure; one of the medical device procedures developed and tested by ECRI is given here as an example; whole procedure and other devices' procedures can be found on ECRI's official site [13].

Qualitative Tasks

"**Mount.** If the defibrillator is mounted on a stand or trolley, examine the condition of the mount. If it is attached to a wall or rests on a shell, check the security of this attachment."

"**Mains Plug.** Examine the mains plug for damage. Attempt to wiggle the blades to determine that they are secure and check that it holds firmly. Inspect resuscitation trolley outlets, including testing for wiring (e.g., using a mains tester) and voltage of all three connections. Also inspect the resuscitation trolley plug for damage."

"**Mains Lead.** Inspect the lead (including resuscitation trolley mains lead, if appropriate) for signs of damage. If damaged, replace the entire lead, or if the damage is near one end, cut out the defective portion. Be sure to wire a new power lead or plug correctly. Check mains leads of battery chargers."

Quantitative Tasks

"**Rate Calibration.** Using a simulated ECG with rates of 60 and 120 pulses per minute, verify that the heart rate indicator displays a rate within 5 percent or 5 bpm, whichever is greater, of the set rate (55 to 65 bpm, 119 to 126 bmp). Verify that the QRS visual and audible indicators are functioning."

"**Rate Alarm.** The setup remains the same as for the Rate Calibration task. Verify that the alarm activates when the input rate is set just below

or above typical low and high rate alarm settings (e.g., 40 and 120 bpm, respectively). The difference between the rate displayed on the rate indicator and that at which the alarm activates should not exceed 5 percent or 5 bpm, whichever is greater."

2.3.3 Association for the Advancement of Medical Instrumentation

The Association for the Advancement of Medical Instrumentation (AAMI) [15] is another association that produces Standards, Recommended Practices, and Technical Information Reports for medical devices.

AAMI's standards and guidance documents for medical equipment reach a broad audience: from the manufacturers who design and produce medical devices in state-of-the-art factories, to the clinical engineering departments where biomedical engineers repair and service equipment, and to where the devices are put into use.

Typical AAMI medical device standard contains labeling, safety, and performance requirements for a particular medical device, and test methods that can be used to verify that the requirements are met. An AAMI recommended practice provides guidelines for the use, care, evaluation, or processing of medical devices. An example of AAMI medical device standards, Standard for Cardiovascular Implants - Tubular Vascular prostheses is included in Appendix.

Although AAMI is a voluntary organization, its Recommended Practices and Standards are considered to be a major resource of healthcare guidelines.

2.3.4 Global Organization Task Force for Medical Devices (GHTF)

GHTF is an informal platform for regulatory authorities and representatives of industry from different countries. The goal of the GHTF is to provide a forum for

national regulatory authorities and industry representatives in the field of medical devices to promote international convergence in regulatory requirements and practices. In particular, GHTF aims to promote the safety, effectiveness/performance and quality of medical devices; to encourage technological innovation; to foster international trade; and to serve as an information exchange forum through which countries developing medical device regulatory systems can benefit from the experience of those with established systems. This is achieved through the development of guidance documents and recommended procedures in order to work towards convergence of the medical device regulatory systems of its members within the boundaries of their legal and institutional constraints [16].

2.3.5 UMDNS Coding

Universal Medical Device Nomenclature System (UMDNS) is a standard international nomenclature and a computer coding system for medical devices that was developed by ECRI. UMDNS is the worldwide nomenclature that has been officially adopted by many nations.

The purpose of UMDNS is to facilitate identifying, processing, filing, storing, retrieving, transferring, and communicating data about medical devices. The nomenclature is used in applications ranging from hospital inventory and work-order controls to national agency medical device regulatory systems and from e-commerce and procurement to medical device databases [17].

UMDNS contains nearly 7500 unique medical device concepts and definitions, and an additional 8000 entry terms to facilitate classifying of biomedical information. A sample bunch of UMDNS codes can be seen in Table 2.1 below.

Table 2.1
Sample UMDNS Codes and Terms.

UMDNS Code	UMDNS Term
11467	Electroencephalographs
11473	Electromanometers
11474	Electromyographs
11479	Electronystagmographs
10134	Anesthesia Units
17877	Ventilators, Negative-Pressure
17865	Ventilators, Jet, Manual
11132	Defibrillators

2.3.6 ISO/TS 19218 (Coding Structure for Adverse Event Type and Cause)

ISO/TS 19218:2005 specifies requirements for a coding structure for describing adverse events related to medical devices. This code is to be used by medical device users, manufacturers and regulatory authorities. A piece of the structure, including 21 adverse event type codes and 37 adverse event cause codes, is sampled in Table 2.2.

The adverse event coding structure specified in ISO/TS 19218:2005 envisages that the reporting of medical device adverse events will originate from one of two sources: the user or the manufacturer of the device concerned. Users may be healthcare professionals or general public. The document provides a coding structure by which an adverse event type and/or the observable cause/effect can be used to collect medical device surveillance information. This Technical Specification can be utilized by the users, manufacturers and regulatory authorities in the following ways:

- Users can report to a manufacturer or a regulatory body a code number to describe an adverse event that will be universally understood by both.
- Manufacturers and regulatory authorities can easily recognize universally understood adverse event types; can assign understood initial assessment cause/effect

Table 2.2
Adverse Event (AE) types, derived from ISO/TS 19218:2005

AE Type Code	**AE Type Term**	**AE Type Description**	**Examples**
100	Abnormal or unexpected biological response	An abnormal or unexpected biological response.	Allergic reaction to a device containing natural rubber latex (NRL), e.g. catheters, drains, or gloves.
110	Computer hardware	Any medical device using computer hardware, (e.g. internal hard disc, external disc drives) where any malfunction of the hardware results in a device failure.	Internal hard drive of the central monitoring system crashes causing the system to no longer function and also resulting in the loss of individual patient information.
120	Connection	An inappropriate capability for connection between: devices, parts, components, or joined elements; not intended to be joined together.	Patient lead is inserted into an electrical outlet.
130	Data output/readings	Data provided by the device or through the use of a device is deficient, e.g. observed aberrant test result possibly leading to inappropriate action or treatment.	Patient identification number is truncated on diagnostic device display unit.
140	Disconnection	The unintended separation of a connection or an unstable connection between two or more parts, (e.g. electrical, mechanical, tubing) resulting in a device failure.	Needles separating from hub. Suture wing separates from catheter.

codes which can be globally recognized by regulatory authorities.

- Both users and manufacturers can apply the use of these codes as part of medical device surveillance or reporting system.

3. METHOD

3.1 Design Criteria

The aim of the study is to design and develop a medical device maintenance management software which will keep record of medical devices, their information, maintenance procedures and repair/maintenance histories; will assign the foregoing maintenance dates and the technician responsible for them; will inform the technician about the maintenance; and will make it possible to carry out and complete the maintenance process remotely, making use of proper maintenance procedures.

We intend to make the study a well constructed preventive maintenance: all actions carried out on a planned, periodic, and specific schedule to keep an item in stated working condition through the process of checking and reconditioning [18].

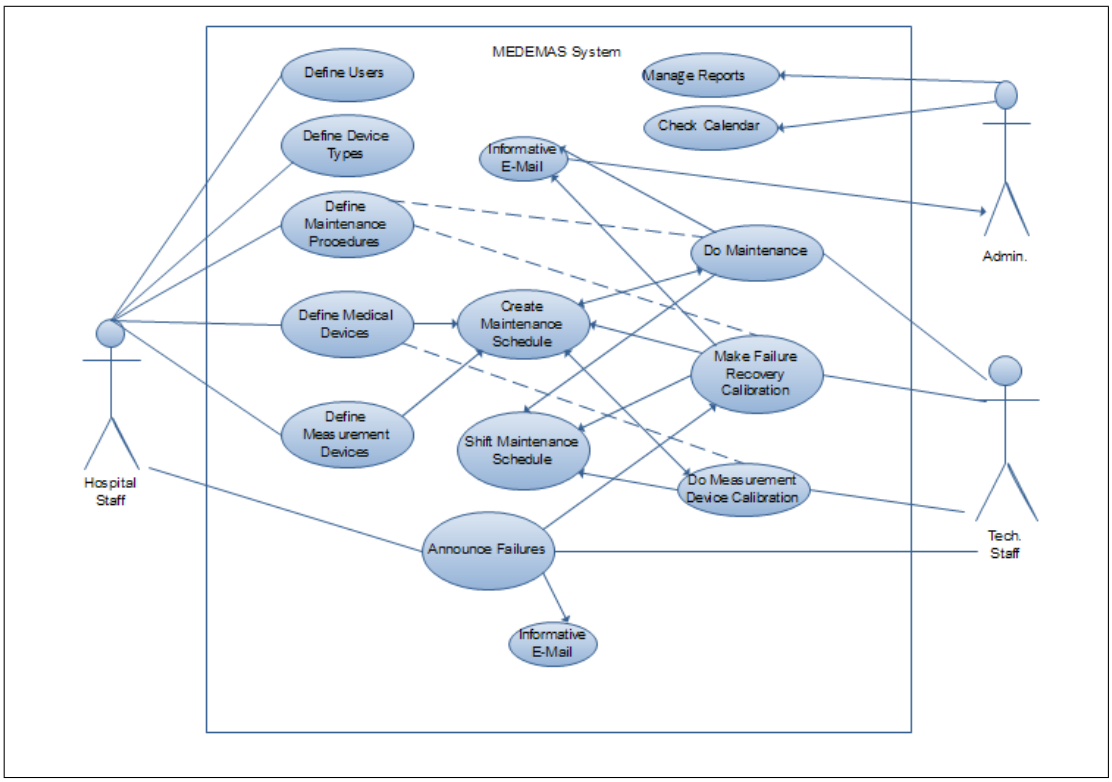

Figure 3.1 Outline of MEDEMAS Structure.

An overview of the MEDEMAS system functionality is drawn as a UML diagram that can be seen in Figure 3.1.

Design Highlights are:

- A strong inventory of medical and measurement devices must be supplied.
- Maintenance procedures must be analyzed, classified and standardized in order to produce a smooth procedure inventory and a smooth maintenance process.
- Maintenance procedures must be defined on device type-basis.
- Devices must be grouped according to their types (sticking to UMDNS coding).
- Medical Device Maintenance Appointments, Measurement Device Appointments, Patient Appointments, Technical Staff Appointments must be available in the system.
- Procedures must lead the staff in maintenance process.
- There must be a failure notification facility.
- Failure notifications must be informed to administrators, and a repair process must be required/triggered.
- All Maintenance, calibration and Repair process results must be kept and must be evaluated.
- If the maintenance fails, a failure record must be created.
- Appointments must be scheduled automatically by the system. Parameters to find a proper time includes the medical device's availability (patient appointments), required measurement devices' availability, technical staff's availability and equal work load distribution.
- Maintenance Appointments must be periodic.

- On appointment creation, all required appointments for the staff, measurement devices and medical devices must be created in order to prevent appointment conflicts.
- Hospital personnel must be in charge of inventory related work, i.e. data entry and management.
- Maintenances should be accessed remotely, as the medical devices are mostly immobile. Wireless Access via PDAs is the preferred solution.
- The design must include a calendar facility.
- Administrators must be supplied with reliable statistics/reports about the performance of devices and the staff.
- There must be an e-mail notification system to remind the maintenance appointments.
- Application must require user authentication.
- Security of the system must be supplied, both in terms of anonymous access and theft.
- Concurrent access by multiple users must be handled to overcome data conflicts.

3.2 System Architecture

Medical devices are located in different places in hospitals, and most of them are impossible to move. Thus, the technical staff will have remote access to maintenance jobs.

Web Applications can be run on any device that has Internet access. An online web application is preferred as Internet is widespread enough, and secure access control is available. Just in time operations prevent data conflict, especially at device maintenances and appointment scheduling.

The nature of the study is a main server remotely accessed by technicians with PDAs through GPRS/WLAN, as shown in Figure 3.2.

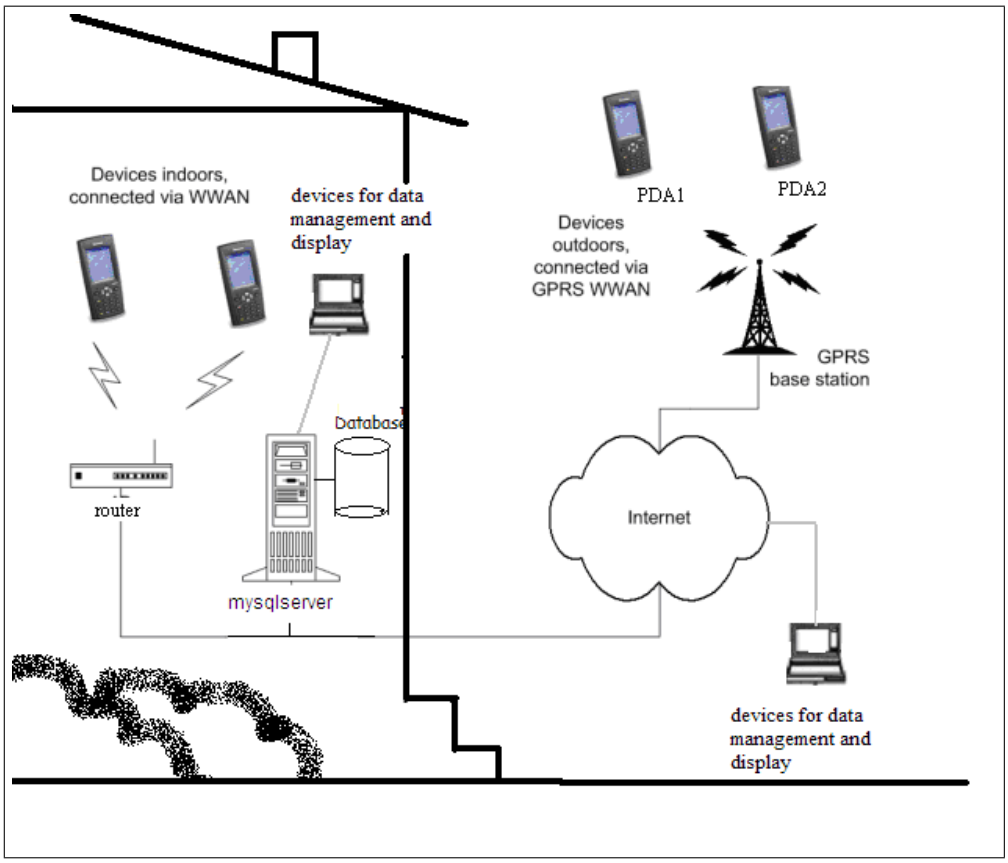

Figure 3.2 Our remote access management scenario.

PDA, short for Personal Digital Assistant is a handheld device that combines computing, telephone/fax, Internet and networking features. A typical PDA can function as a cellular phone, fax sender, Web browser and personal organizer.

GPRS, General Packet Radio Service, which is a standard for wireless communications, is an efficient use of limited bandwidth and is particularly suited for sending and receiving small bursts of data, such as e-mail and Web browsing, as well as large volumes of data.

Main server is also accessed by hospital personnel and directives for data entry, management and reporting facilities. This is done by computers through Internet or

intranet. While the data management is done via a windows application using intranet, administrator access especially for reporting is through web application.

Data is stored and managed using MySQL. Applications were implemented using C# and .NET, if required HTML and JavaScript were also used.

3.3 System Modules

MEDEMAS is divided into two modules.

(Data) Inventory Module is a windows-based application that will be used by hospital personnel. The mission of this module is to manage all data inventory processes required by MEDEMAS system.

Medical Device Management Module is web-based and will be used by technical staff for maintenance and repair processes. This module also includes administrative functions like calendar, statistics and reports which will be used by administrators.

There is a third batch application that regularly sends reminder e-mails.

3.3.1 Inventory Module

Inventory Module is used for database management; adding, deleting and updating are basic and common operations. The databases that are managed through inventory module are:

i. Medical Device Type Database that groups medical devices based on their types; type code relies on UMDNS coding system.

Device type is also determinative in maintenance procedure selection as pro-

cedures are specific to medical device types. This database includes a parameter for measurement frequency.

Maintenance frequency is affected by medical device related factors like recommendations of the manufacturer and advisory bodies, age of the device, past history of the device, experience and knowledge of the user, and frequency, environment and nature of use [19]. Besides, The Joint Commission allows inspection intervals to be adjusted based on risk and hospital maintenance data and, thus, the hospital does not have to default to manufacturer recommendations. The Reports/Statistics we supply will help in determining such a need.

ii. Medical Device Database keeps inventory of medical devices. When a medical device and its accessories are handed over to the user, a new record should be initiated. The record should include the information of [20]:

- initial configuration (products, interfaces, accessories, software, documentation),
- dates of initial delivery, handover & first use,
- inventory number,
- responsible department/person,
- place where used,
- product identification,
- manufacturer/supplier,
- (links to) operational maintenance procedures,
- preventive maintenance scheme,
- nomenclature item, e.g., according to GMDN, ECRI, UDMNS,
- current situation (under maintenance/ maintained/not maintained/under repair etc).

The database holds informational data about the devices such as device ID, device name, location, brand, situation etc. Devices will be classified and will be given IDs in Department-UMDNS-Device Order format.

Other required information for devices, like breakdown history, maintenance history, maintenance appointments are distributed among databases created for themselves. Those databases can be reached through (are linked to) Medical Device Database but they are not manageable by Inventory Module.

iii. Procedures Database is designed for maintenance procedures. This database is especially important as procedures are in the middle of our design and implementation; in other words they determine our system schema. Procedures have relation with most of the other databases like medical devices, measurement devices, medical device types, users, device appointment databases and maintenance result databases. Definitely, all maintenance-related processes carried out by users make use of the procedures.

The medical devices regulations require a manufacturer to provide *'all the information needed to verify whether the device can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely at all times' [21].*

The maintenance and repair instructions will give information of:

- Safety checks
- Internal and external quality control
- Calibration requirements
- The measurements to be done
- The standard values for measurements

In order to decide to database structure of maintenance procedures, a number of physical device maintenance procedures were analyzed. Analyzes were also helpful in deciding maintenance process carry-on type: step by step guiding of technical staff. Doing so, it would be assured that no step was skipped, no measurement was overlooked.

Our procedure database consists of device type (UMDNS) specific procedures that are defined step by step. Each step has its own operation type, requirements and its expected values.

In order to standardize procedures, operation types and requirements are classified. Definition of procedures is made by users, like as the other inventory databases/definitions.

iv. Measurement Device Type groups measurement devices. Each (maintenance) procedure step may have its own measurement device type. In appointment creation, an available device of that type is reserved for the appointment. Measurement Device Type structure is almost the same of Medical Device Type Database.

v. Measurement Device Database keeps measurement device inventory. It is the same of Medical Device Database. The only difference is that these devices are used for measurement in maintenances.

vi. User Database contains both technical staff and personnel data. User type and user authentication level are important parameters to distinguish technical staff and hospital personnel and to arrange allowed processes.

vii. Breakdown Type Database contains failure codes and definitions. ISO/TS 19218 (Coding structure for adverse event type and cause) standard is used for failure type definition.

viii. Company Database is used to define company names. This information is used when maintenance /repair process is out-sourced and the responsible staff is

from another company. Brand Database keeps data of brand names and makes up the brand name parameter of device definitions.

ix. Department Database is used to define departments of the hospital. Department information is actively used in device ID generation.

x. Buildings Database contains building names in the hospital complex.

xi. Conditions Database is for definition of condition types like Active, Passive, Failed etc.

xii. Notifications Database keeps any notification or information message that is to be sent by e-mail or SMS.

All Company, Department, Buildings and Brand; especially Conditions and Notifications Database are designed for uniqueness and dynamicity considerations. This way, updates will be very easy to handle; only a change in the related database will be enough. In addition, especially in case of Notifications Database, hard-coding of messages is prevented and dynamicity is supplied.

Medical device maintenance appointments, breakdown notification records and maintenance records; measurement device maintenance appointments and records will all be held in separate databases. However they cannot be accessed through Inventory Module; they are filled by applications when related processes are completed.

3.3.2 Medical Device Maintenance Module

This web module contains technical staff processes; calibration, maintenance and repair. Administrator processes like calendar, statistics and reports are also included here. Access to processes is regulated with user authority levels.

i. Maintenance and Calibration

Calibration is the setup process that is done as the device is first installed. In maintenance and calibration processes the staff is guided by the maintenance procedures defined previously. At each step of the procedure, measurement data is required from the user and it is compared with the procedure requirements for evaluation or consistency. Result of the maintenance is determined at the end of the process and the administrative staff is informed about it. All process data is recorded and used for reporting or tracking later.

If needed, a new maintenance schedule for the device is formed automatically at the completion of maintenance. Since measurement devices are also devices that are expected to function properly, they have their own maintenance calendars too. We prepared a design which is a replica of medical devices'; however current treatment is much simpler for measurement devices. Their maintenances are made via web application either.

ii. Breakdown and Repair

As soon as a breakdown is recorded, the device is marked as "Failed", and there is a proper after-repair calibration facility. The records of breakdowns are held as information of nature and duration of the failure are especially important in evaluating device performance.

Failure Database keeps information of failed device, failure time, recovery time, notifier user, failure type, failure status and any extra explanation mentioned.

iii. Appointments

Maintenance appointments are created automatically by the system. Appointments should be periodic processes and in practice they are planned yearly; all appointments of the year are scheduled in one go.

The parameters to determine a proper date includes availability of medical devices, availability of measurement devices and availability of technical staff. Equivalent work load distribution is aimed in selection of medical devices and technical staff. Rescheduling in cases of maintenance delay or device failure is another concern of appointment design.

Appointments Database must keep information of medical device, appointment date and time, responsible staff and status of the appointment. There is also a Measurement Device Appointments Database which keeps measurement device appointment information as the same as Appointment Database. The two databases are linked with the measurement number kept in both of them.

iv. Schedule/Calendar

A calendar that shows appointments on a daily/hourly schedule provokes visual efficiency. The design includes construction of a calendar which works in different aspects: shows appointments on personnel basis and shows appointments on device basis.

v. Statistics/Reports/Analysis

Statistics are for evaluation, comparison and decision making. We will evaluate maintenance results and failures and will prepare reports for administrators. These reports will assist in deciding fate of the devices or the staff. Reports will give clue of staff and device performance, device failure rates and failure durations. Thus, they are important in terms of risk management and benchmarking.

vi. Announcements/Notifications

Appointments must be reminded to the responsible staff when due date is close enough. The staff must also be reminded of the maintenances that they missed. Similarly, administrators should be informed about delayed maintenances. The planned

solution is a batch process that runs once a few hours and sends reminder e-mails.

3.4 Database Relations

In order to build up a smooth system, the first step is designing a reliable infrastructure. Our design contains a number of databases that should be filled up by users. Some of these databases are required for inventory and the others are planned for informative or parametric concerns.

Each database has a primary key. Some tables also have foreign keys as they keep parametric values.

For Failure, User, Building, Department, Company, Brand, Notification and Status Databases the primary key is a code given by the user.

For medical and measurement device types, the primary key is the UMDNS number, again typed by user. For medical and measurement devices the primary key is the device ID (BMAE) which is a combination of Department Code, UMDNS Code and Order. Status, brand and building codes are foreign keys to related databases.

Procedures Table has UMDNS code and procedure order number as the primary keys since procedures are device type specific and are defined in steps.

For appointments database, the key is maintenance number, a unique sequential number automatically given. Device ID and responsible are foreign keys to medical device and user databases.

Measurement device appointments database's primary key is measurement device ID - maintenance number pair, as each appointment may have different number of measurement devices assigned. Responsible code is foreign key.

Maintenance Results Table's key is maintenance number - procedure order combination as each step's result is recorded separately. Device ID and user code are foreign keys.

(Medical Device) Patient Appointments Table's key is medical device ID and appointment date - time to avoid appointment conflicts.

3.5 Security and Authentication

Each user has an ID, a password and an access level. Components of the system s/he can use are limited with his/her access level. Passwords are encrypted.

Web application is protected from illegal access, i.e. direct access to intermediate windows. We also included idle session logout to the system.

3.6 Concurrent Access

For web applications that allow multiple, simultaneous users to insert or update same data, there is a possibility of data conflict. In our case, there is another point: our appointments have duration. Thus, appointments of especially a measurement device/user can intercept without causing any problem on database-level.

MySQL automatically handles concurrent access to a database; if there are multiple access requests, they are queued and performed in sequence; first come first served. This is the first layer of prevention strategy we will rely on. Since MEDEMAS forces user authentication, especially in case of maintenances, user-specific access will help in terms of conflict prevention.

Third layer of prevention will be on database level. The databases will have an

"availability status" column. For the selected record, this field will be updated by the one 'first came' and all following accesses will check this field for availability, and skip to another available record. When the winner completes its process, it will free the record by emptying status.

Taking into consideration crash/uncompleted access cases, availability status will be emptied after a proper period of time.

4. CASE STUDIES/RESULTS

We designed and implemented a medical device maintenance management system (MEDEMAS) that:

1. provides a data pool of medical devices, all required information about these devices, and the maintenance procedures for the devices,
2. contains complete repair and maintenance history of medical devices,
3. creates optimal maintenance schedule for the devices automatically,
4. enables the service technician to carry out and report maintenance/repair processes via remote access,
5. supplies the administrators with the statistics/reports to make evaluations and device or staff comparisons, and
6. informs the technical staff about their appointments; technical and administrative staff about missed appointments.

MEDEMAS is centered on a main server which is both a MySQL server for data storage and a web server for remote access.

MySQL was chosen heavily because it is open source, easy to use, fast, reliable and preferable for web applications. It is the world's most popular open source database software, with over 100 million copies of its software downloaded or distributed [22].

The results of the study will be explained in three sections. Section 4.1 will give details of the Windows component that is used for inventory operations; Section 4.2 will give details of remotely accessed web component for maintenance and related processes and Section 4.3 will shortly summarize the mail notification process.

4.1 Windows Application for Inventory

The inventory application helps in constructing required data infrastructure for the main device management system. It is a Visual Studio Windows Application; it runs on Windows machines. The target users of this application are either Biomedical Department employee-if there is any, or IT Department employee, or any other personnel who is responsible for data entry and management.

At the beginning, the data structure for the system was constructed. Required databases, contents of databases and relations between databases were determined. In order to make the system more flexible and dynamic, as many data groups (databases) were formed as possible. The databases differ in complexity: some are very simple like Status Definition and some are very complicated, such as Procedure Definition.

Inventory Application is used to make insert and update operations on databases. Users can select among allowed definition forms when they enter the system.

Figure 4.1 Inventory Application Entrance Screen.

The application is password protected; initial screen a user meets is Inventory

Management Entrance screen seen in Figure 4.1. Users can fill in user-password pair and continue, or can make password operations. If the user forgot his/her password, s/he can require a new password; a random password is generated and e-mailed to the user. If the user wants to change the password, a change password screen appears, requiring user information and new password twice, and sets new password as entered (Figure 4.2).

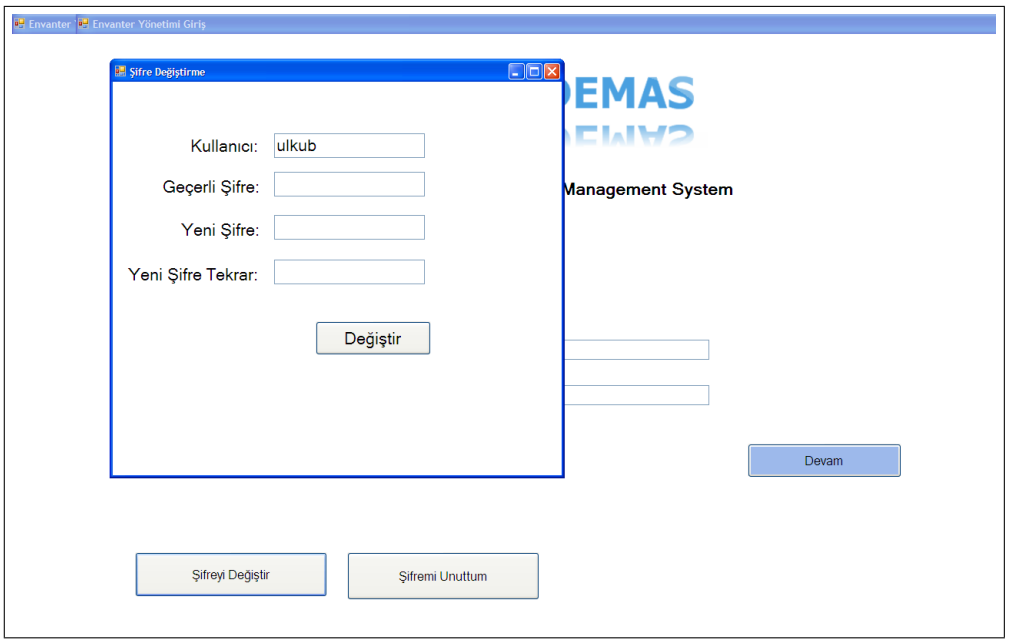

Figure 4.2 Password Change Screen.

Following Entrance Screen, a database selection screen appears (Figure 4.3). Here, user selects among databases that can be accessed, and s/he is directed to related database update screen.

We present list of all records of the selected database at first, and user can add new record or update records. New record and update screens are the same, except for changing ID/record code is not allowed in update operation. Though we will talk about "defining" here, we will mostly show update screens to embody real data. For once, list of all records that brings user to the definition window will be showed (Figure 4.4); it should be known that all definition windows stated here have a preceding "list of all" window.

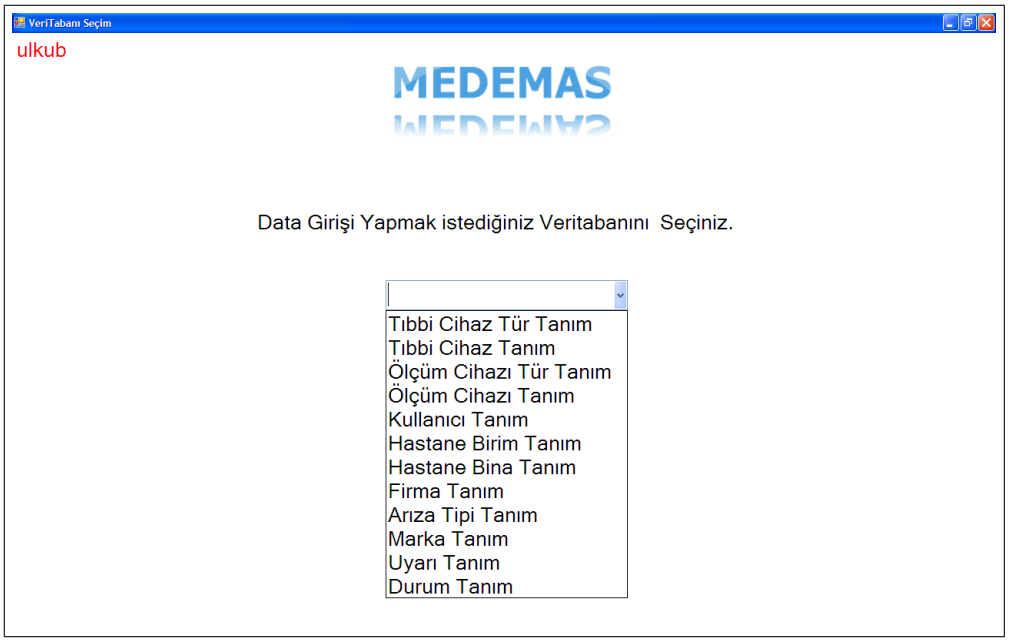

Figure 4.3 Database Selection Screen.

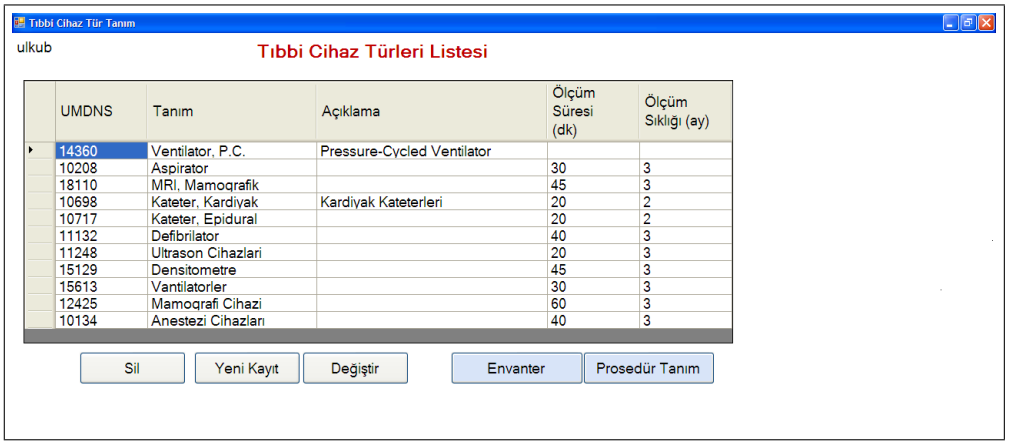

Figure 4.4 List of All Medical Device Types.

There are two groups of devices in the system, medical devices and measurement devices. Measurement devices are used for measurement in maintenance process of medical devices. In order to define a device, we must have its type defined. Both device groups are defined in a similar manner. Device Types are defined first and devices belonging to those types after.

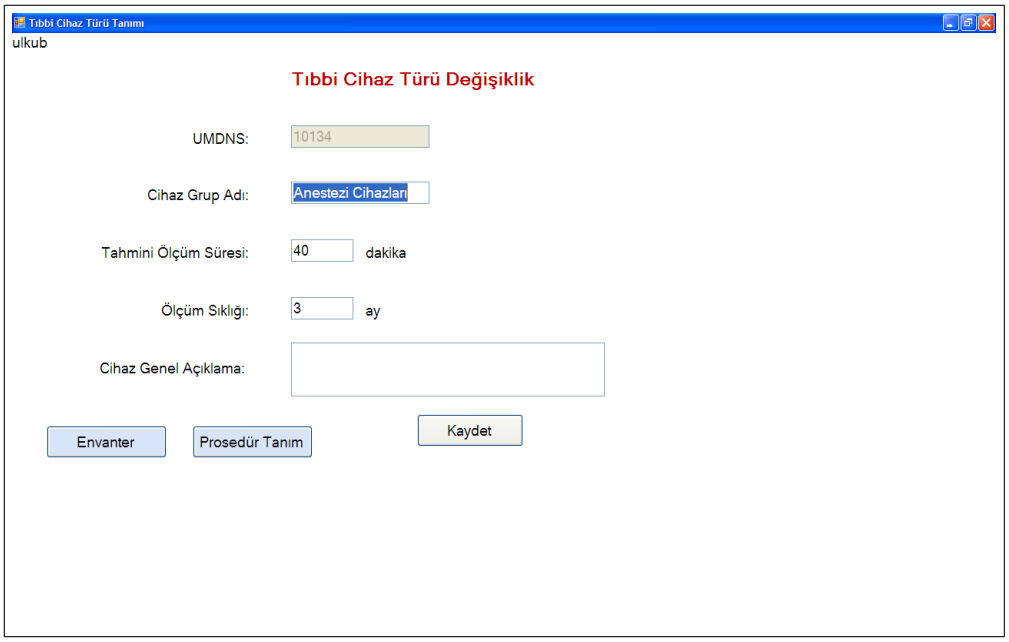

Figure 4.5 Medical Device Type Definition Form.

4.1.1 Medical Device Type Definition

In Medical Device Type definition (Figure 4.5) we use UMDNS codes as device type code. Since maintenance procedures are defined on device type basis, two parameters are essential here. Measurement duration determines maintenance appointment's end time. It is useful both in searching for an appropriate time and in fixing and appointment.

Measurement Frequency, in months, tells how often maintenance is done. Automatic scheduling process makes use of this parameter as determining the next appointment's date adding this value of months in between. With the facility buttons on this screen the medical devices of the specific type can be viewed and maintenance procedure belonging to this device type can be listed and managed.

Deletion of device type is not allowed if there exist any medical devices of this type.

4.1.2 Medical Device Definition

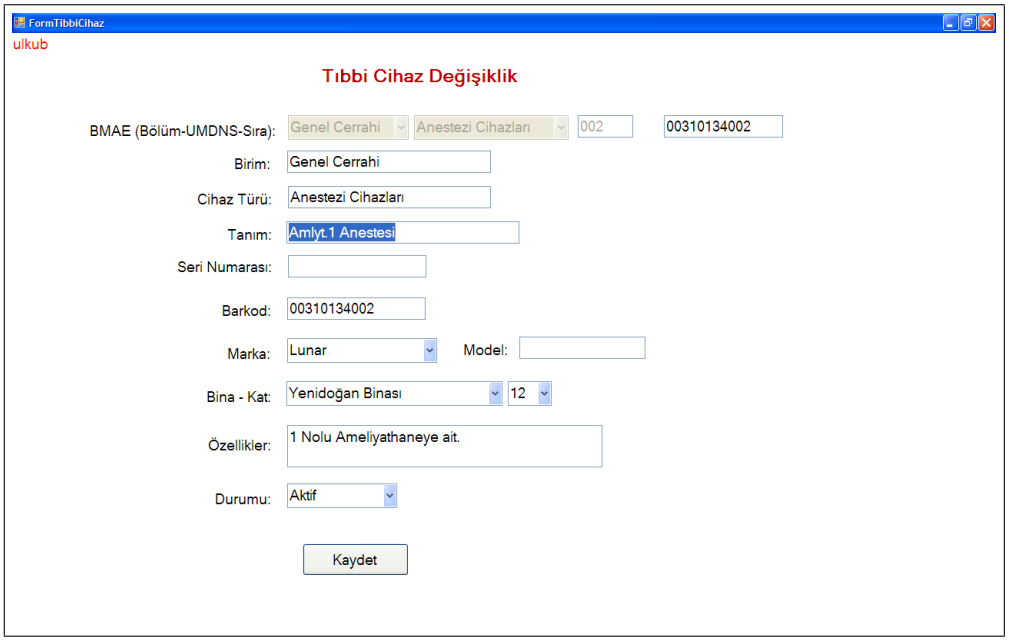

Figure 4.6 Medical Device Definition Form.

Figure 4.5 shows Medical Device Definition Form, with an anesthesia device previously defined on it. Medical Device ID is formed using UMDNS ECRI device coding system. As stated above, UMDNS codes of medical device types are defined in Device Type Definition. When a new device is entered, we supply a device ID as department code (3 digit) - UMDNS code (5 digit) - order. According to department and UMDNS selection, device order is automatically given. Users only see Department name and Device Type name selections but system saves their codes in background. Definition form displays Device Type, Department and device ID additionally.

Serial number, barcode, location, brand, model and status are other information about the device gathered from the user. Device initial delivery date is recorded as device definition date.

As soon as a new device definition is completed, its setup calibration appointment is automatically scheduled on that day. Details of automatic appointment scheduling will be given in 4.2.10.

On deletion of a medical device, all maintenance appointments of this device, including user and measurement device appointments are deleted either.

4.1.3 Procedure Definition

In order to decide to database type of maintenance procedures, a number of physical device maintenance procedures were analyzed. Analyses were also helpful in deciding the maintenance process carry-on type: step by step guiding of technical staff. Doing so, it would be assured that no step was skipped, no measurement was overlooked.

Each medical device type has its own maintenance procedure. Thus, procedure definitions should be made on a device type - step number basis.

In order to prevent confusions, we preferred to put Procedure Definition Form link into Medical Device Type Definition Form. So, users only see one procedure at a time. Screenshot of Procedure Definition Form can be seen in Figure 4.7.

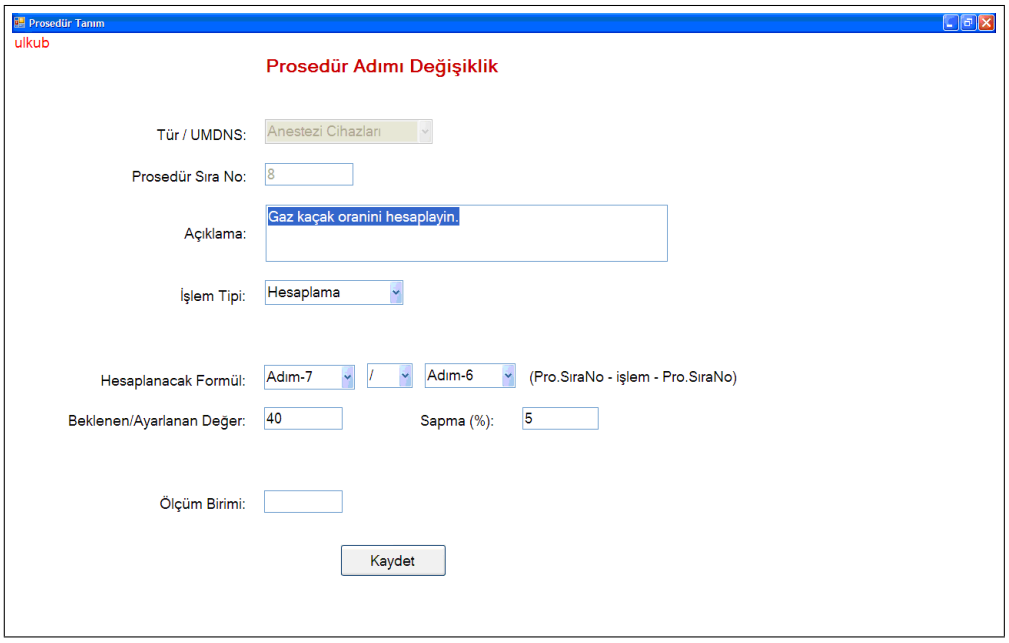

Figure 4.7 Procedure Definition Form, Screenshot of 8th step of Anesthesia Device Procedure.

Procedures are defined one step/operation at a time and step number is automatically increased.

Explanation field is to write the measurement instructions for that step. This explanation guides the technician in maintenance; it is displayed on maintenance (step) screen.

We classified procedures and ended up with 4 basic operation types that a step could contain. Checkbox, Yes/No, Measurement and Calculation. There can be two types of measurement results provided by the procedure: value and percent error; and value range (max-min value limits). These parameters are used in evaluating the results.

While Measurement and Calculation require measurement data; Checkbox and Yes/No preferably want it. There is another parameter; measurement unit identified for that measurement (step) which tells technician in what unit the result is wanted. Calculation operation type lets us define a formula dynamically. It makes use of previous steps' measurements and offers a formula in Operand1-Operator-Operand2, all selective, like Step1 + Step2. We did not deal with complex operations as one operation was enough in most cases. Computation is made and noted down by the technician.

"Measurement" operation type necessitates measurement device type. This is the device type to be used for that measurement and is a critical parameter in maintenance planning. In scheduling process, any measurement device of that device type is investigated to be available at the proposed time of maintenance.

4.1.4 Measurement Device Type Definition and Measurement Device Definition

These two definitions are nearly the same as medical device ones. The difference is that there is no maintenance procedure definition for measurement devices. However,

our infrastructure supplies possible future measurement device procedures.

Like medical devices, when a new measurement device definition is completed, a configuration calibration appointment is automatically assigned on that day. Deletion of a measurement device is allowed only when there are no medical device maintenance appointments using it. On deletion, its own maintenance appointments are deleted. Figure 4.8 and Figure 4.9 depicts Measurement Device Type Definition and Measurement Device Definition Forms respectively.

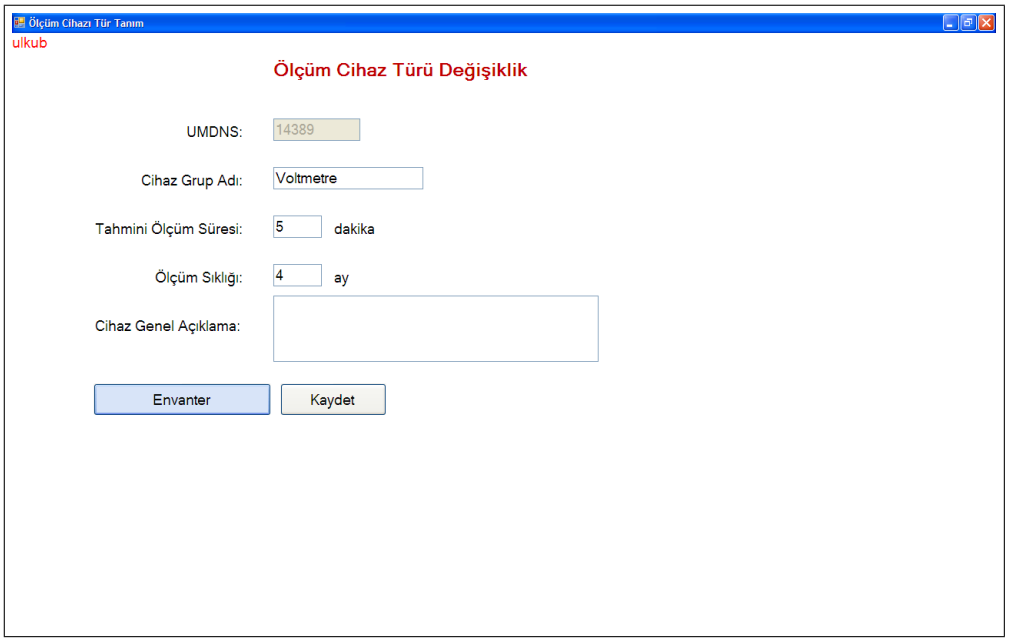

Figure 4.8 Measurement Device Type Definition Form.

4.1.5 Failure Definition

Failure Definitions are used in failure reporting. ISO/TS 19218 (Coding structure for adverse event type and cause) standard is used for failure type definition. It helps in analyzing and comparison of failures. Code, Definition and if needed explanation are gathered from the user (Figure 4.10).

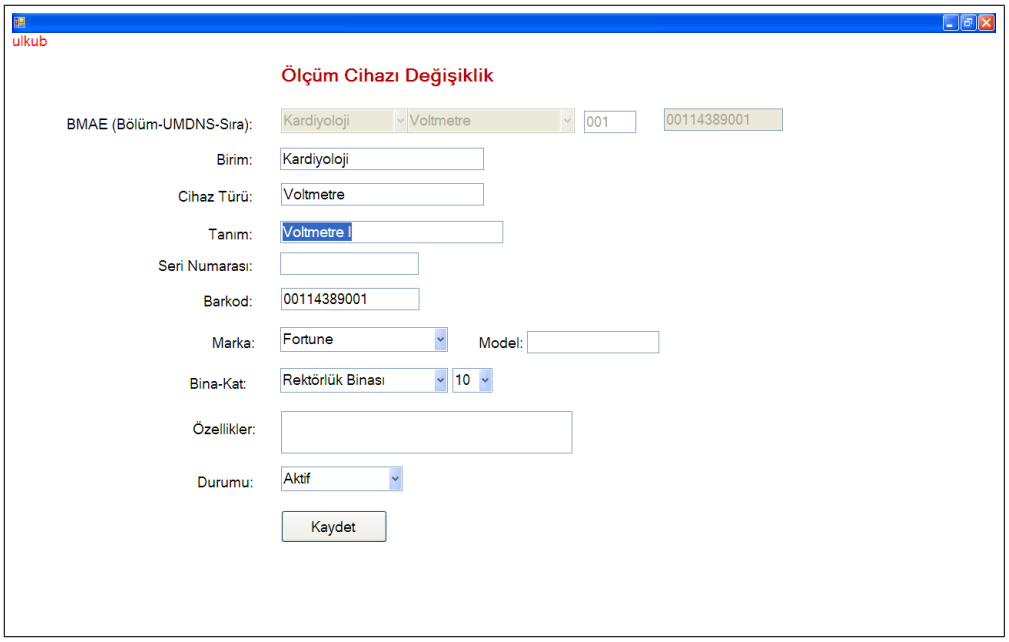

Figure 4.9 Measurement Device Definition Form.

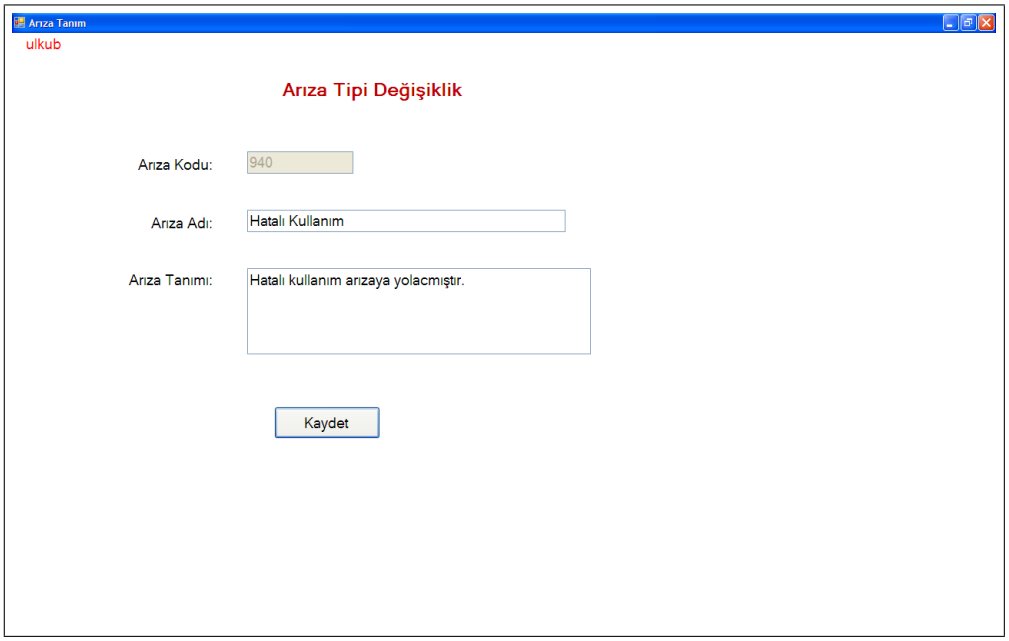

Figure 4.10 Failure Type Definition Form.

4.1.6 User definition

Since the application relies on user-authentication, user type is specified in definition: (ordinary) user or technical staff. Similarly, authentication level is determined and used to control access to system. Especially in case of technical staff, the user can

be from another company. Thus, user definition includes interior/exterior user selection and department/company selection associated with the selection. User password is given on creation and all the password management is done by the user himself on the rest. Screenshot of user definition form is given in Figure 4.11 below.

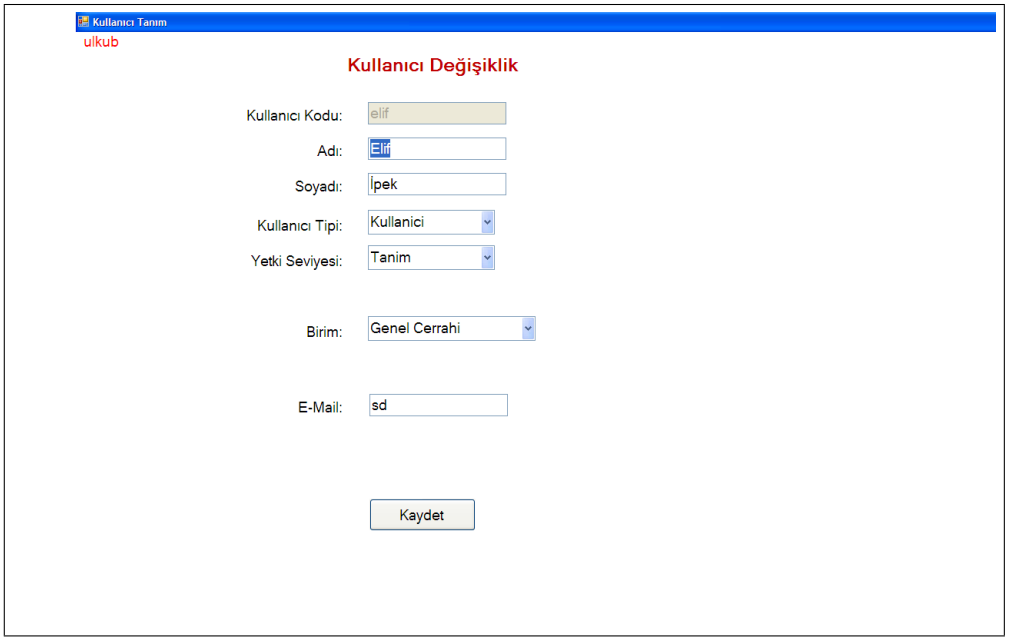

Figure 4.11 User Definition Form.

4.1.7 Department definition:

It is straightforward, departments of the hospital are defined and the recorded department codes are used in medical device ID definition. Figure 4.12 shows department definition; requiring department code, name, responsible and phone information. Figure 13.

4.1.8 Company Definition:

Company Definition is made to supply a company data pool for user definition. Company code, name, address and contact information like phone, e-mail, contact person are definition parameters as can be seen in Figure 4.13.

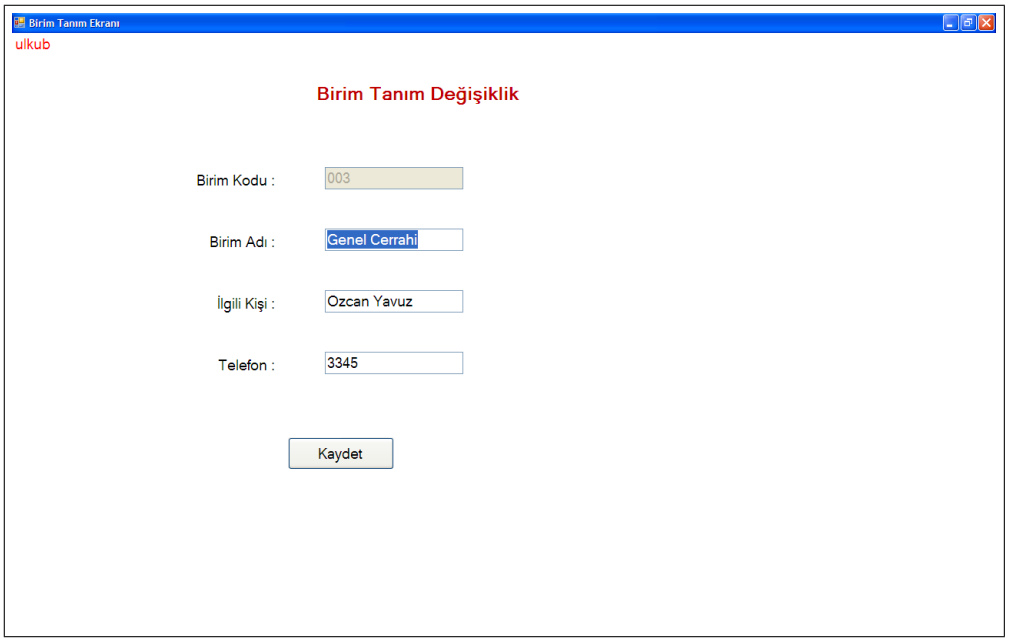

Figure 4.12 Hospital Department Definition Form.

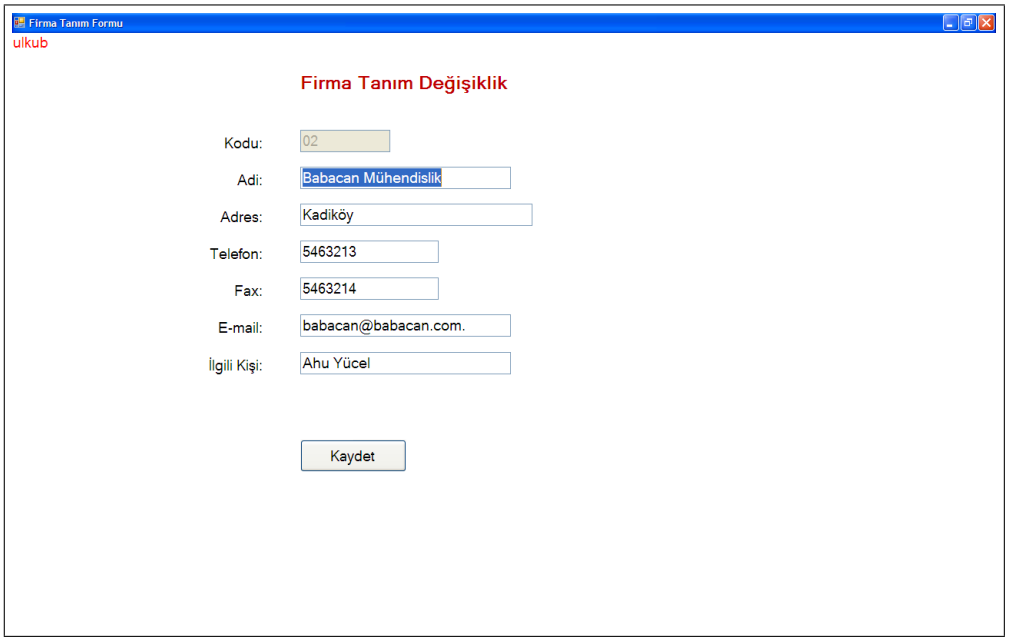

Figure 4.13 Company Definition Form.

4.1.9 Brand Name Definition:

Brand name definitions made are used in medical device definition; the brand is selected from supplied ones; Figure 4.14 shows brand definition form

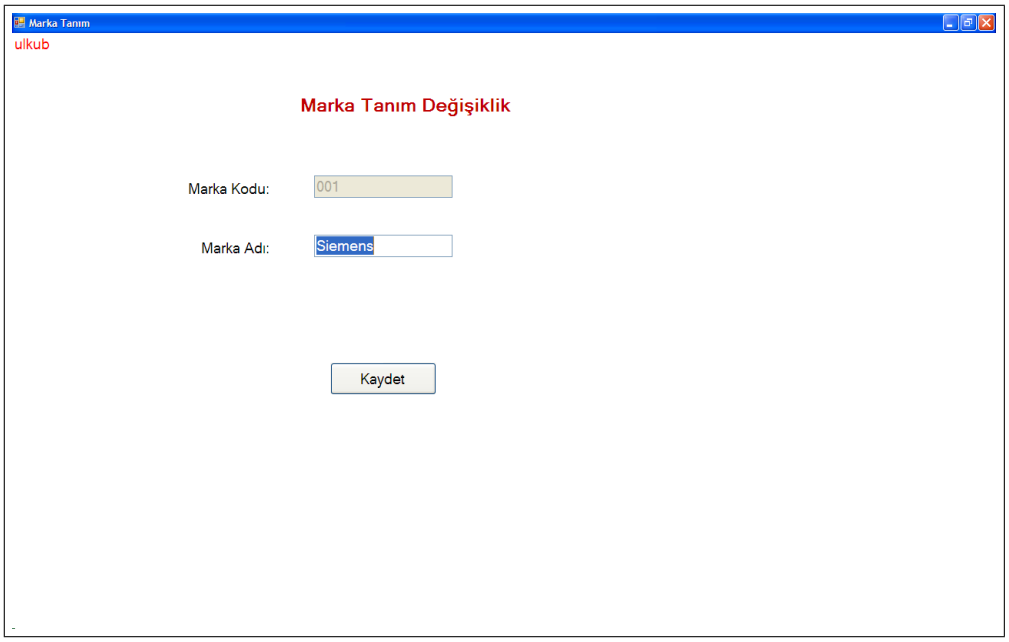

Figure 4.14 Brand Name Definition Form.

4.1.10 Building Definition

Recording codes and names of hospital complex buildings standardizes building parameter of medical device definition. This method prevents ambiguity and makes it possible to sort devices according to buildings if needed. Figure 4.15 shows how building definition is made.

4.1.11 Warning Message Definition

Warning Message Definition (Figure 4.16) is added in order to bring uniqueness and user-intervention. Hard coded messages are unable to change, and also may vary. SMS/Email type of messages can be formed and are made use of.

4.2 Web Application for Remote Access

This module is a Visual Studio Web Application implemented in ASP.Net C#.

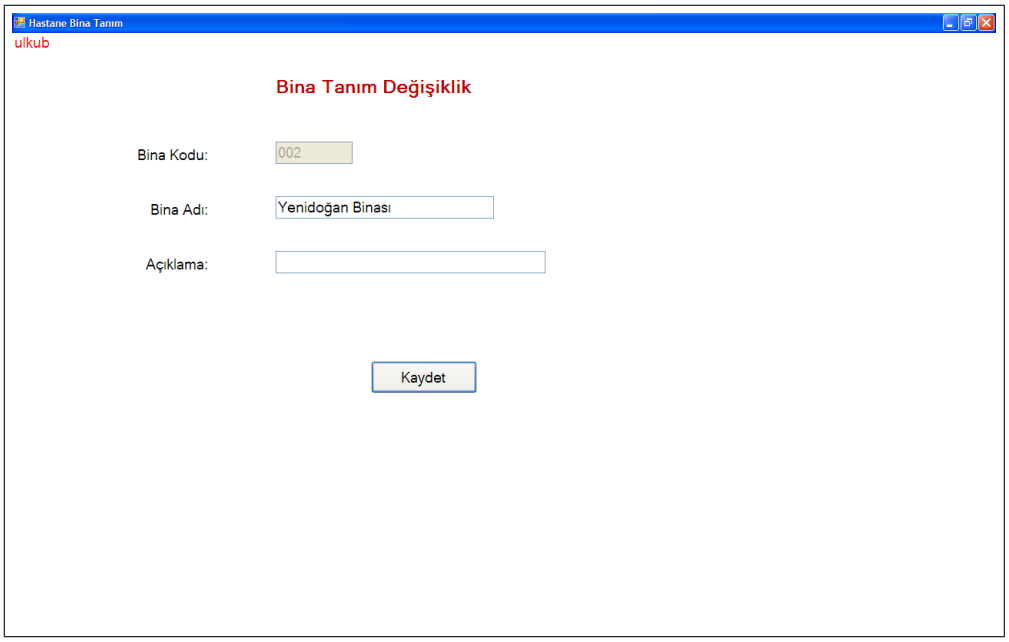

Figure 4.15 Hospital Building Definition.

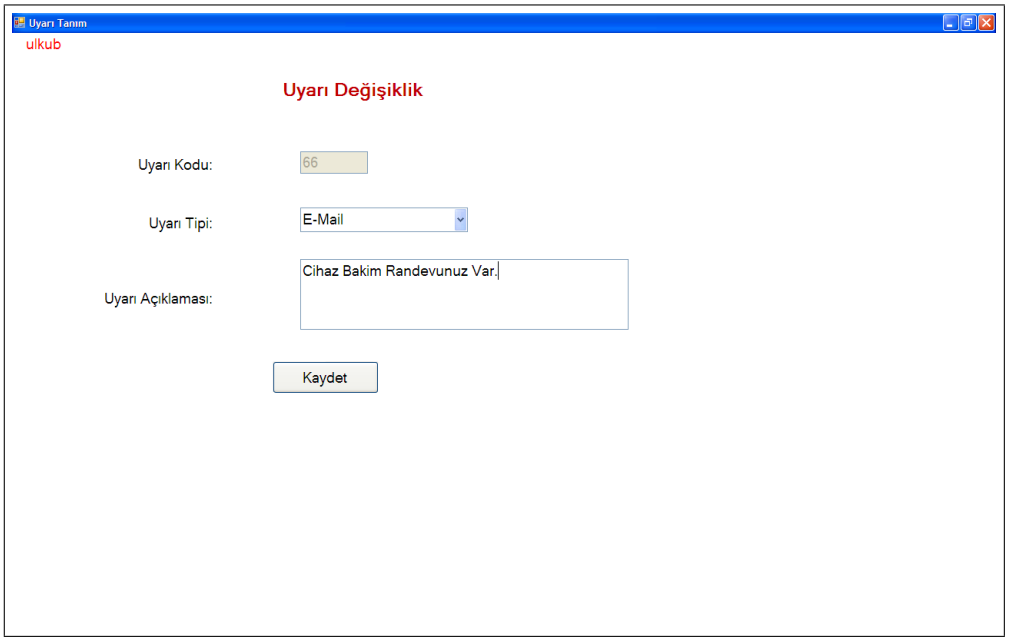

Figure 4.16 Warning Message Definition Form.

Application was chosen to be online web application as Internet is widespread enough, and secure access control is available. Just in time operations prevent data conflict, especially at appointment scheduling.

The application can be run on any device that has Internet access and an In-

ternet browser. Tests with laptops, smart phones and PDAs were successful. It can also be run on different browsers like Internet Explorer, Firefox, and Opera without any problem.

Web application is aimed to run on both PCs, for the administrators, and on PDAs, for the technical staff. A slight interface difference is observed between two, in order to fit the application in PDA screen. We needed remote access as the technical staff would make calibrations in place of medical device, for easy access it would be best to provide them with a mobile device and remote access. The mobile device chosen in scope of this thesis was Motorola Symbol MC70 Handheld Mobile Computer. This device is perfect for mobile users and has plus facilities like laser scanner and phone.

Since the plan is to use the application on mobile devices, native mobile application was another solution. Native application would mean being specific to a type of device, so when the device type or even device model was changed, we would have to change our implementation: extra cost, extra work, and extra time. In our case, it was more reasonable and easier to let it work on alternative devices smoothly, instead of depending on a single device, thus web application was the most efficient solution in our case.

Maintenance web application was at first planned for only device maintenance by technical staff, but as the project advanced, new access requirements and facilities emerged. We decided to add whole maintenance processes to web component and used windows component only for making definitions. Thus, web application is used for medical device calibration and maintenance, measurement device calibration, failure submitting, failure recovery, schedule monitoring and reporting/analysis. New medical device definition is also included to allow the technical staff to identify a fresh device just in place. The whole menu is not accessible by everyone; user authentication and authentication level driven access is used.

Start page of web application is presented in Figure 4.17. Changing password and resetting password processes are the same of inventory application's. Once the

Figure 4.17 Web Application Start Window.

user logs in, a welcome page appears with all operation options on it (Figure 4.18). This is, in fact, our main window.

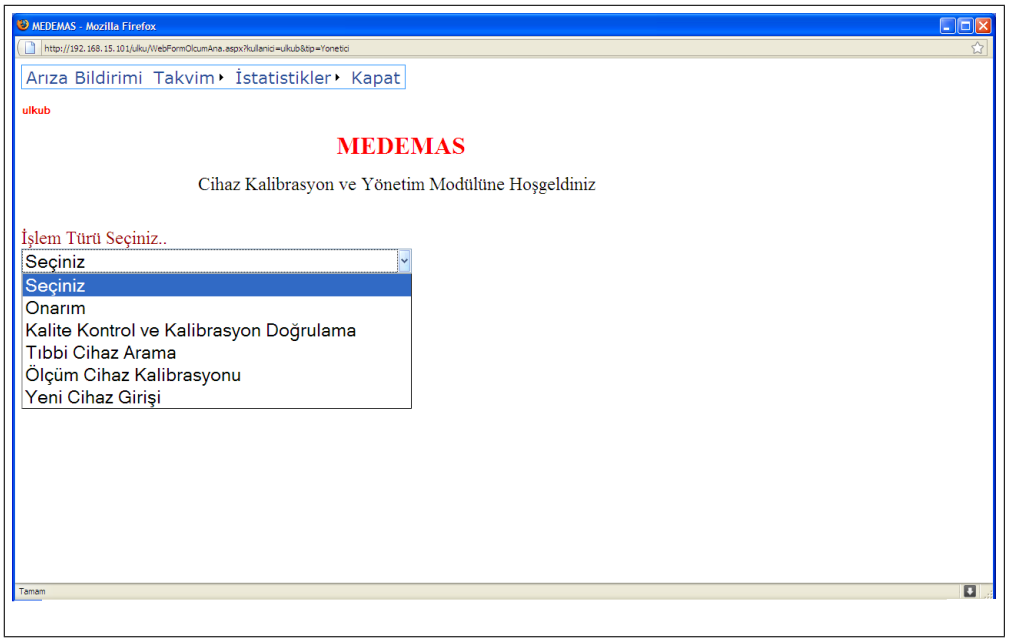

Figure 4.18 Main Operations Page.

4.2.1 Maintenance and Calibration Process:

If the user selects "Kalite Kontrol ve Kalibrasyon Dogrulama" from selection combobox, the calibration/maintenance appointments that are already delayed or are within same month of the current month are listed (Figure 4.19). If the user is a technical staff member, only the appointments that belong to him/her are shown; administrator-level users can see all appointments listed in date order.

Figure 4.19 Maintenance Appointments.

For each appointment entry, two operations are provided. First one is viewing the measurement devices that are assigned for the specific maintenance appointment. At the time of medical device appointment creation, user and measurement device appointments are also created, thus it is possible for the user to see which devices will be used for the calibration/maintenance process. Figure 4.20 shows the measurement devices that are assigned for the maintenance appointment of device 'MRI' on 06.06.2010; displayed by clicking Measurement Devices button.

Second operation is evoking maintenance process itself. Maintenance takes start by displaying the first step of device management procedure. First step of anesthesia

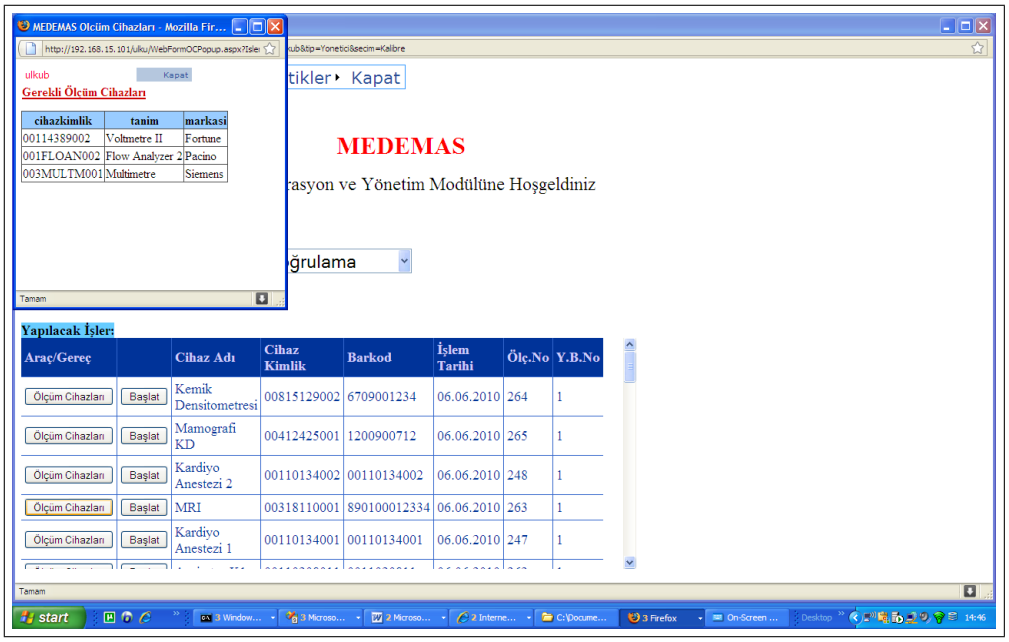

Figure 4.20 Assigned Measurement Devices Popup.

procedure can be seen in Figure 4.21, which is a typical maintenance procedure step. General information about the device is supplied at the top. Step explanation says what to do in this step. If operation is Checkbox or Yes/No type, proper selection boxes appear. Here, operation type is checkbox, and the user is required to enter calibration value. Right to the calibration value textbox, measurement unit that was determined previously -in procedure creation- can be observed.

The process continues step by step. The user is not allowed to switch to the next step without providing required information. At the end of each step, data is directly sent to the server, step result is computed and the process is recorded in Maintenance Results Database. Each measurement or data supplied by the user is evaluated and compared with what the procedure step definition states. If it is within the range, step is marked as 'Pass', otherwise it is marked as 'Fail'. Each step result is recorded in measurement results database. If there is any failing step at the end of operation, the whole process Fails. Figure 4.22 shows the third step of anesthesia device maintenance process, having operation type Yes/No.

As soon as the process is completed, all related appointments - medical device,

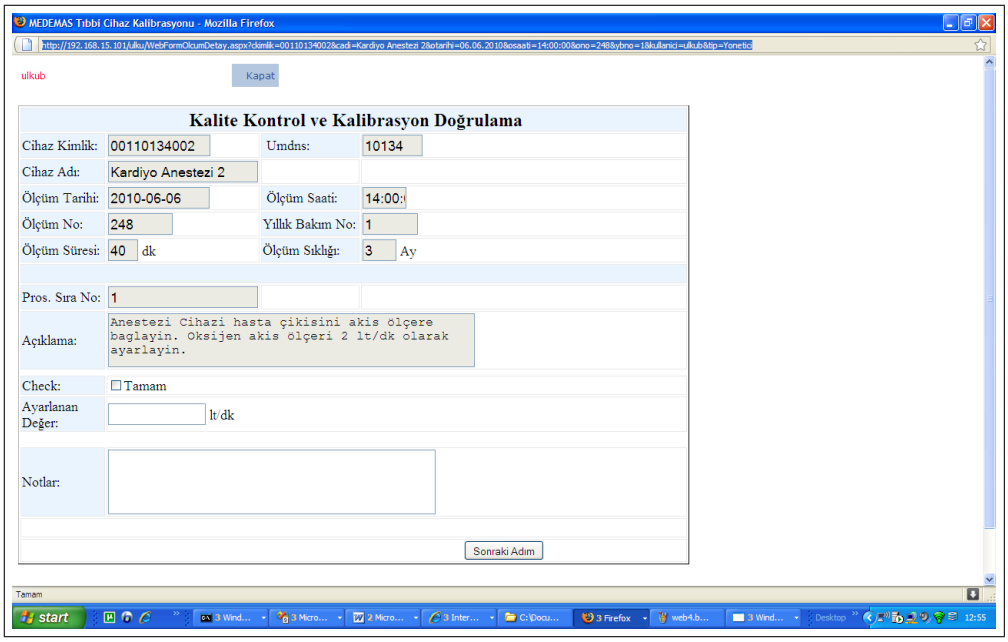

Figure 4.21 First Step of Anesthesia Maintenance Procedure.

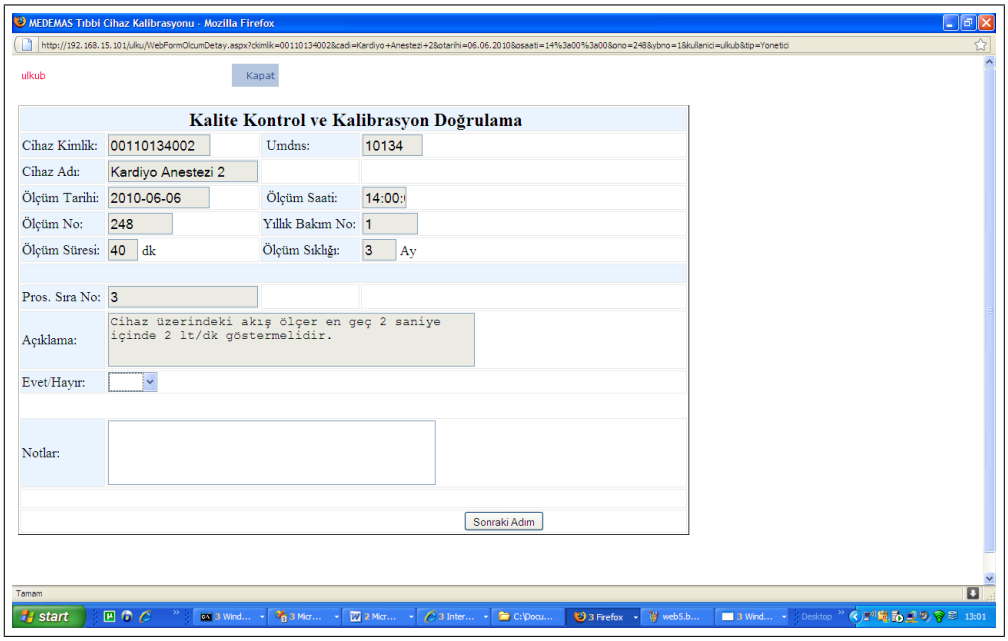

Figure 4.22 Third Step of Procedure for device Cardiac Anesthesia 2.

measurement device and user appointments- are deactivated. Maintenance schedule of the medical device is examined. If there is no remaining future appointment then a one-year maintenance schedule is automatically prepared. If the device has still appointments, then the current date is compared with assigned date of the maintenance just completed. If there is a delay of 30 or more days, then the remaining appointments

are shifted, sticking to the measurement frequency parameters of that device type. Details of automatic appointment scheduling will be given in 4.2.10.

An information mail is sent to the responsible administrator stating that maintenance is completed. If somehow, process cannot be completed, the appointment stays active, and user can re-process the maintenance. Thus, at the very beginning of the maintenance process we look for and delete any maintenance (step) result entries belonging to this appointment.

4.2.2 Failure Recovery

Failure Recovery selection lists the medical devices that have been announced as damaged (Figure 4.23). There is no scheduled recovery process for the devices of this list as return date is not certain. Any technician can handle the devices and take over failure recovery process any time. First staff starting the process marks the failure record as unavailable, so no one can start another recovery process on it. A failure is also available in case it has been marked unavailable for more than 2*maintenance duration.

On Failure Recovery window, the medical device types that are necessary for recovery calibration can be displayed (Figure 4.24), and calibration process can be carried on.

Recovery calibration process, as shown in Figure 4.25, is similar to maintenance process stated above. When the process is completed, device appointments are examined to see if there is any maintenance appointment missed while the device was not in use. If any, they are canceled. A new 'completed calibration appointment' is recorded for the process just finished. If the medical device has no remaining appointments, a 1-year maintenance schedule is prepared. If there are future appointments, they are not disturbed, shifting is not in question. Lastly, device failure record is deactivated.

Figure 4.23 By selecting Recovery, list of all failures appear.

Figure 4.24 Types of measurement devices which are required for recovery calibration of anesthesia device Amlyt. 1 Anestezi.

4.2.3 Measurement Device Calibration/Maintenance:

Measurement Device Calibration/Maintenance option lists the measurement device appointments scheduled, as shown in Figure 4.26. Again, users can only see the

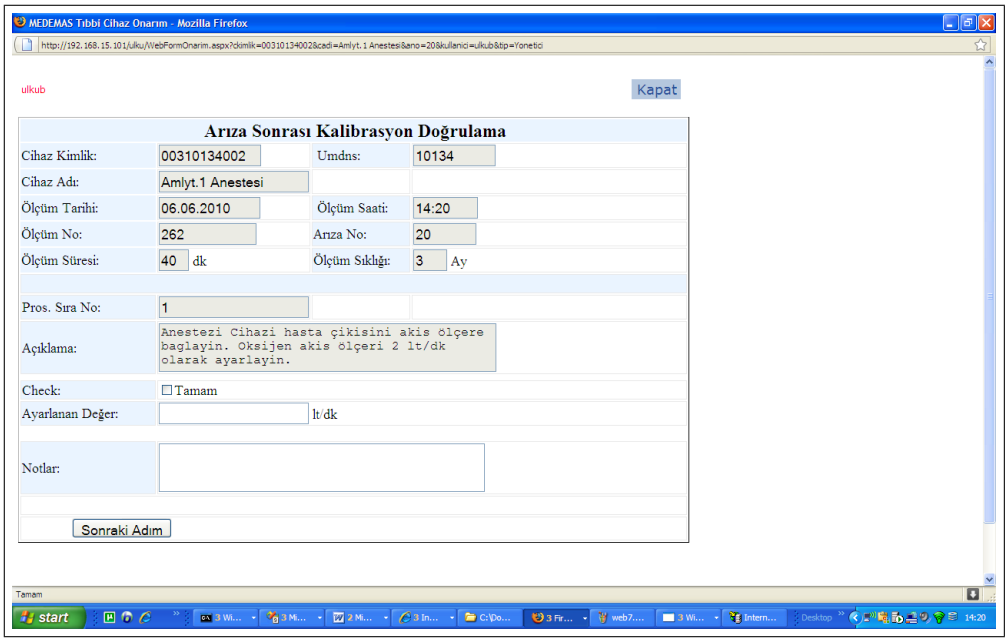

Figure 4.25 Recovery calibration process for Amlyt. 1 Anestezi.

appointments that their authentication level allows.

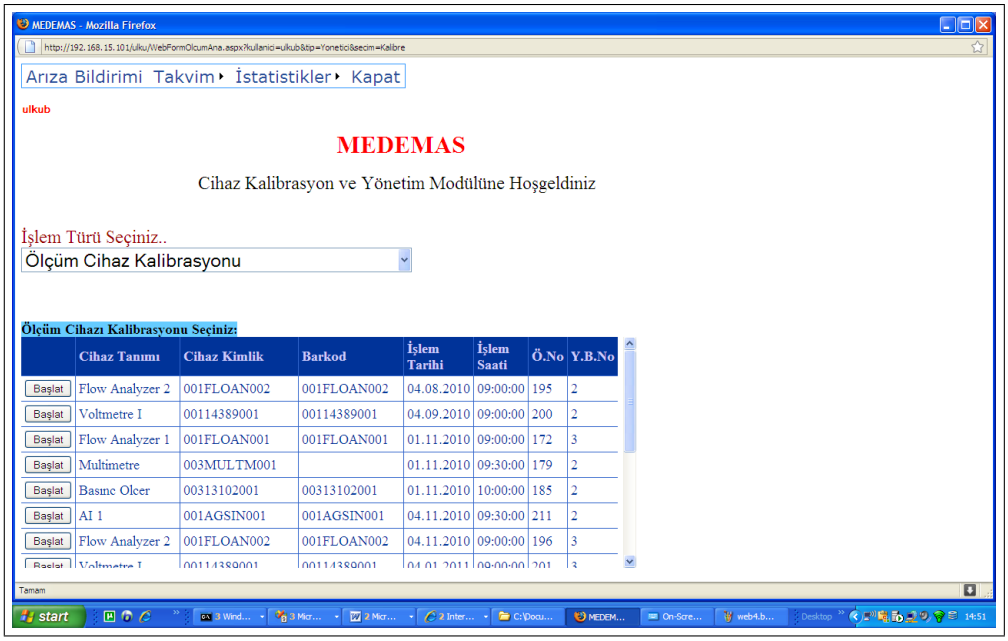

Figure 4.26 Measurement Device Maintenance Appointments.

Although we have designed a measurement device infrastructure that owns a maintenance management structure similar to that of medical device's, for the moment there are no maintenance procedures for measurement devices. Thus we prepared a

maintenance result form as in Figure 4.27 which takes a pass/fail result and any extra explanation the technician wants to add. At the end of calibration, calibration schedule is detected and if the device has no remaining calibrations scheduled, a 1-year schedule is created. If this calibration was delayed 30 days or more, remaining calibrations are shifted.

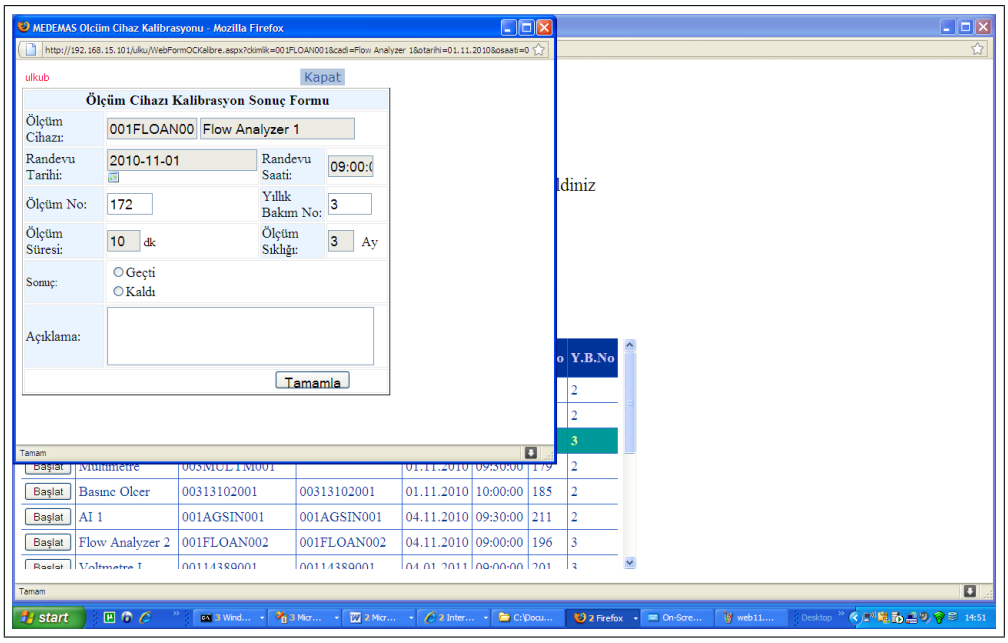

Figure 4.27 Measurement Device Maintenance Form for Flow Analyzer 1.

4.2.4 Medical Device Query

A specific device can be searched and displayed with this facility. Both Device Barcode and Device ID can be used for searching. If device exists, its information is brought. User is also supplied with device maintenance history, device failure history and Device maintenance schedule. They can be expanded using related buttons; a sample page for device query is put in Figure 4.28.

Individual reports of past maintenances can be created and printed here. Details of the maintenance, measurements and evaluation are placed in the report (Figure 4.29).

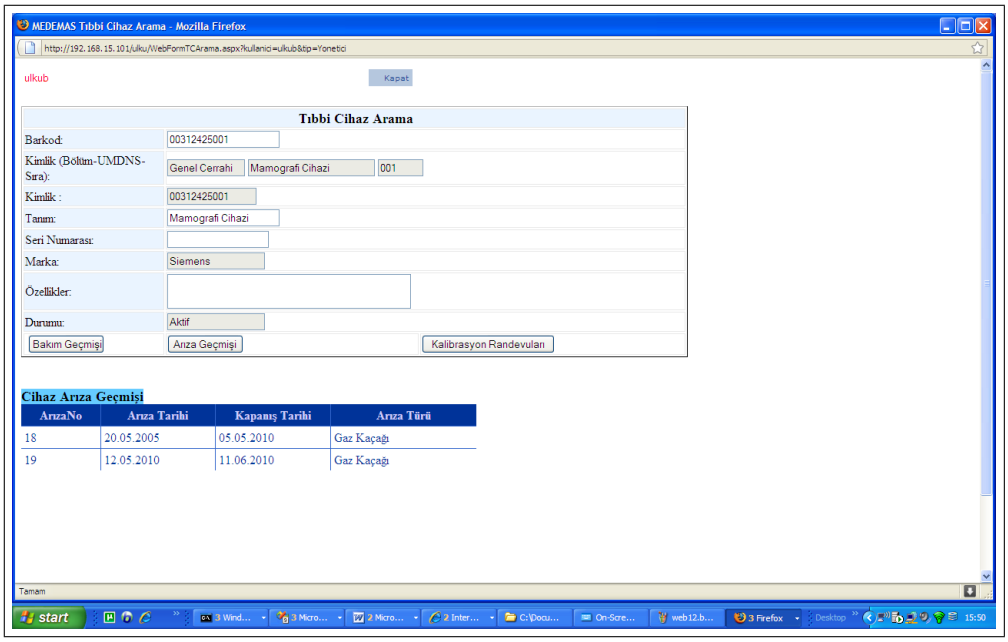

Figure 4.28 Device with ID 00312425001 is searched, and its Failure History is expanded.

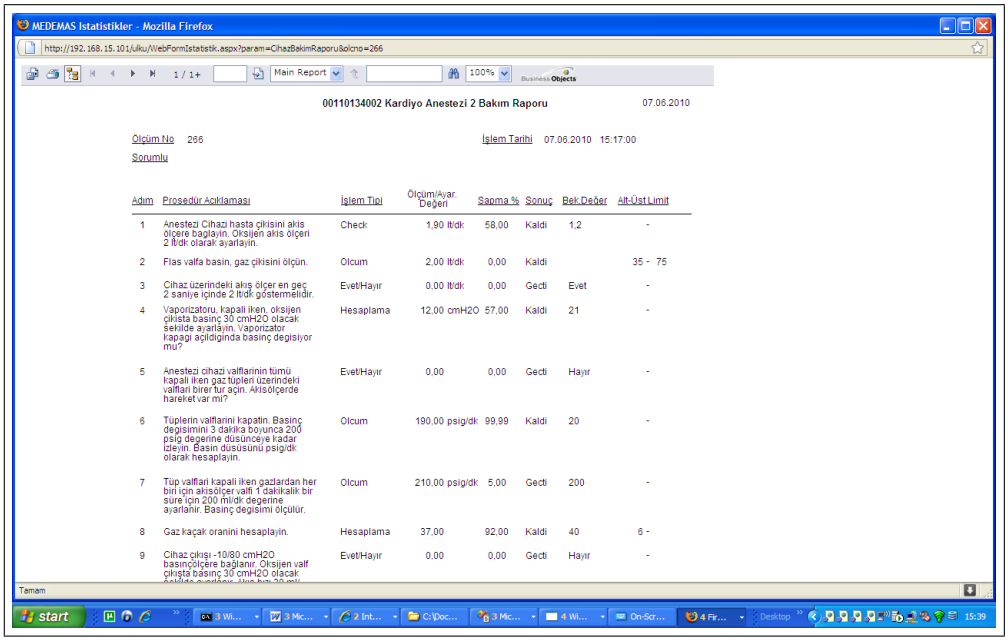

Figure 4.29 Sample Maintenance Report.

4.2.5 Medical Device Definition

We included new medical device definition in web application as an exception. The driving force is that a newly arriving device might be recorded just in place and

just at that time. This process is the same as the definition process of the inventory component.

We included new medical device definition in web application as an exception. The driving force is that a newly arriving device might be recorded just in place and just at that time. As it can be understood from Figure 4.30), this process is the same of the definition process on inventory component.

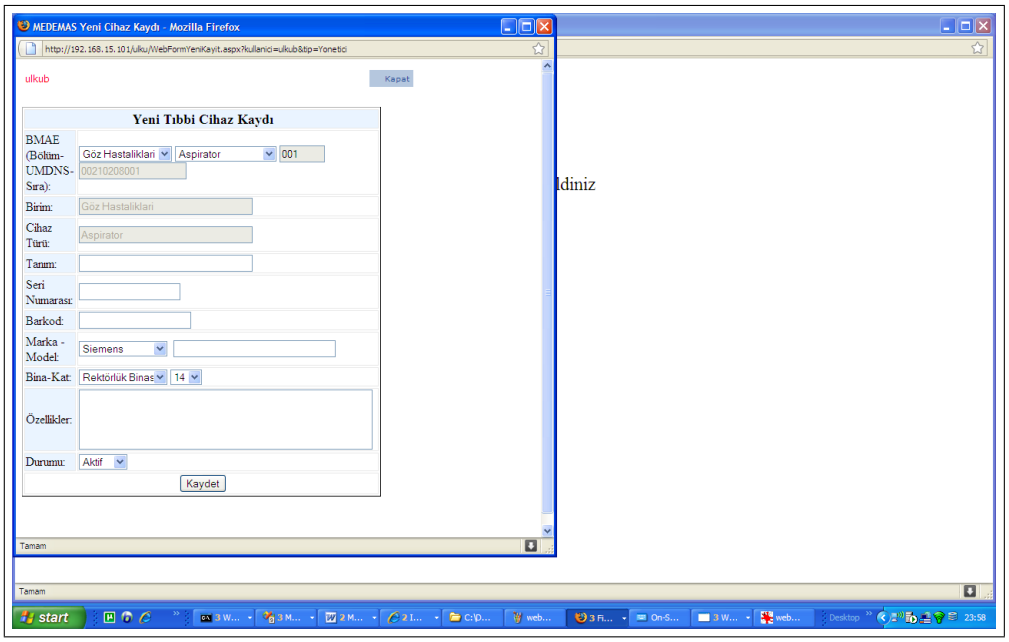

Figure 4.30 New Medical Device Definition Form.

4.2.6 Failure Recording

As seen in Figure 4.31, Failure Recording is used to record any medical device failure; any user can use this facility. Device and failure code are requested from the user; the failure codes fit international standards.

Failure notification sets the device status as "Failed" and this device cannot be accessed until its recovery calibration is made. As soon as the failure is recorded, the device occurs in failure recovery list.

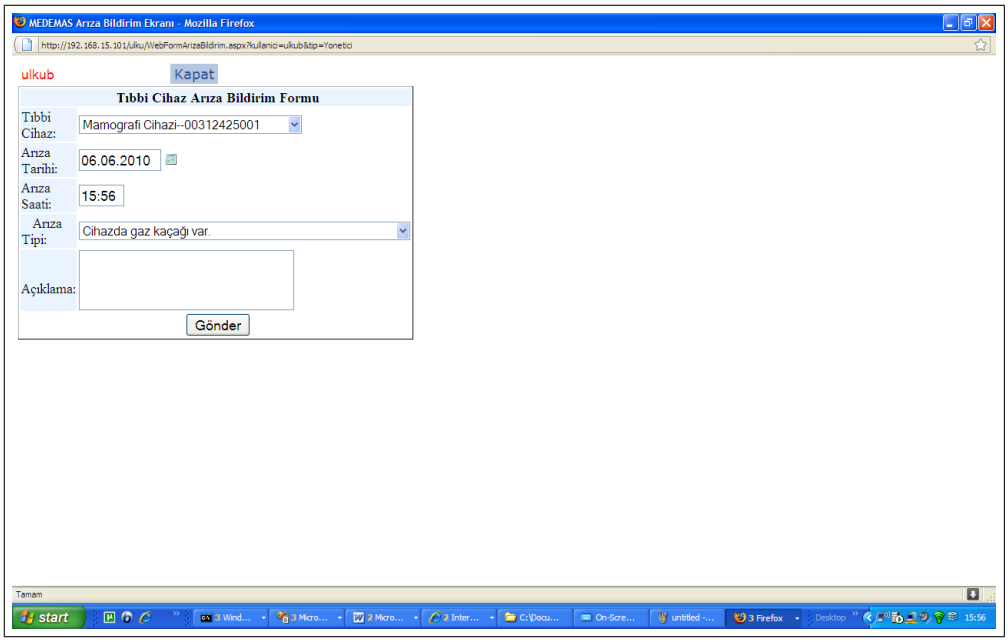

Figure 4.31 Medical Device Failure Recording Page.

Although it is not accessible, the device's maintenance schedule is kept during failure. Because, the failure is an exception and we do not want to disturb yearly planned schedule. Duplicate failure notification for a device is prevented.

4.2.7 Calendar

Calendar is a visual facility. For this process, DayPilot Lite calendar application is modified. DayPilot Calendar is an Outlook-like day/week view and DayPilot Lite is the open-source version of it. A date picker for calendar beginning date and a selection box among Daily, 3-Day, Weekly, 2-Week and Monthly calendars are added. On the calendar, when an appointment entry is clicked, a small information pop-up including appointment date, time, device and the responsible staff appears. Personal Calendar is for non-administrator users, shows only the appointments of the current user. Person Based Calendar adds a technical staff selection list on the form. The appointments of the selected person are shown. All Persons shows all maintenance appointments together. Device Based Calendar is used to select a device and to show its appointments.

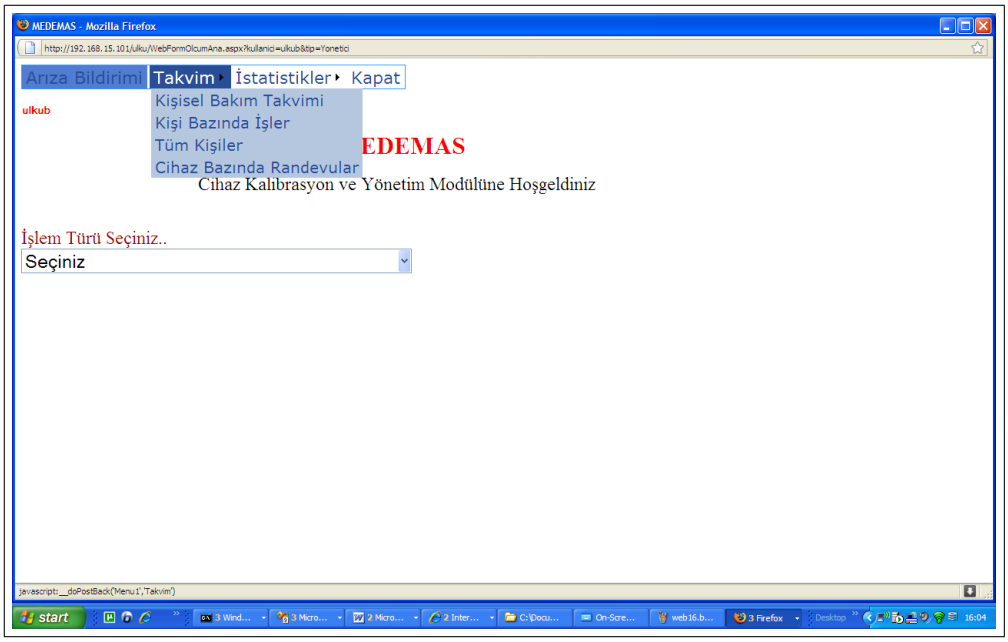

Figure 4.32 Calendar Choices.

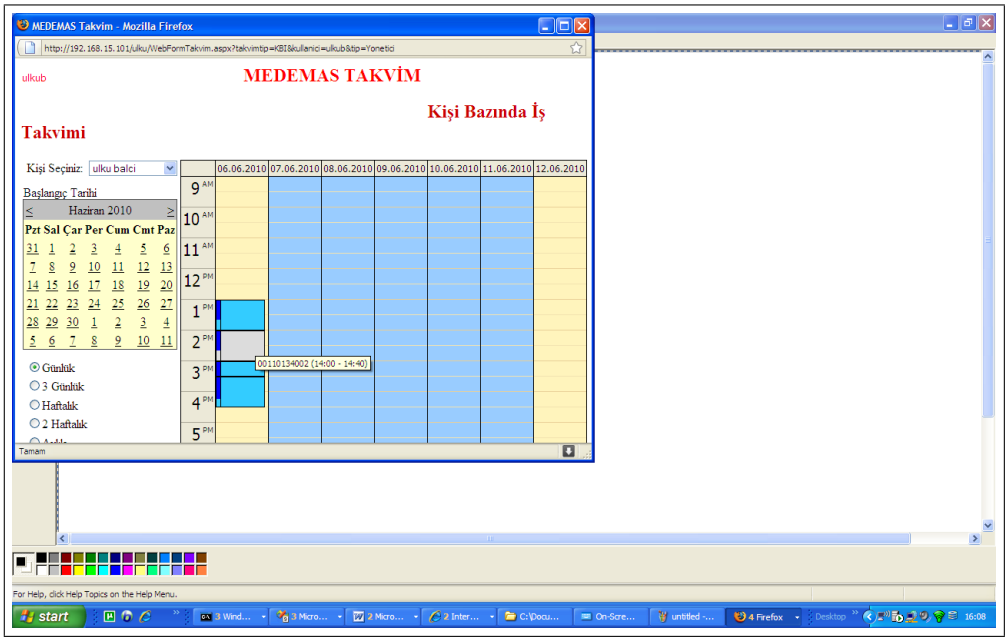

Figure 4.33 Calendar for user ulku balci.

To exemplify, Person Based Calendar is shown in Figure 4.33. A default 7-day calendar for user ulku balci is shown, hovering mouse on appointment activates tooltip as medical device ID - appointment time pair. In Figure 4.34, short information about that appointment is displayed by clicking on the appointment entry.

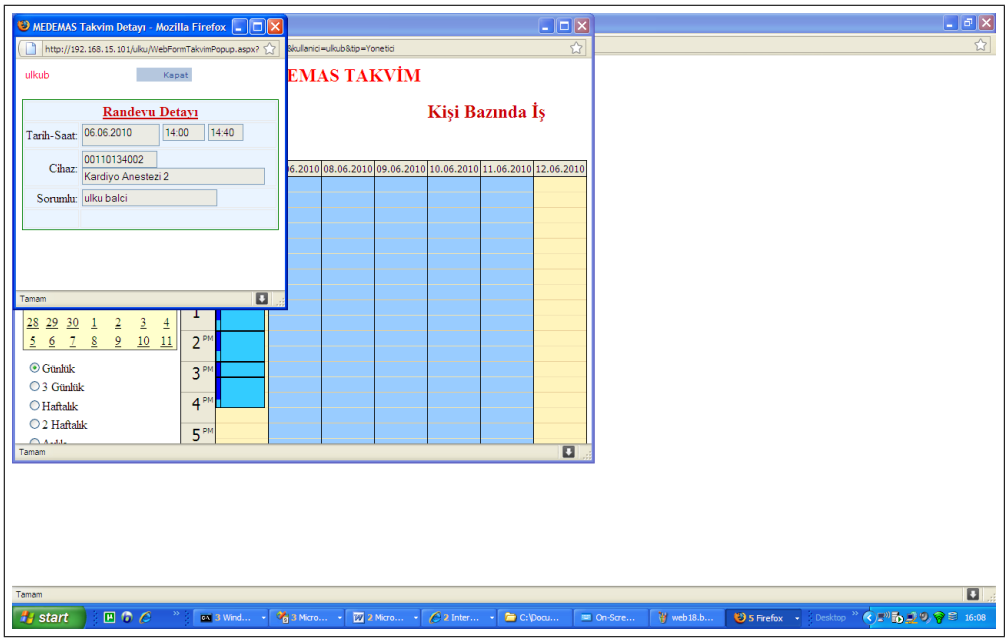

Figure 4.34 Clicking on appointments, brief information about that information can be displayed.

4.2.8 Statistics

Statistics are aimed to be helpful in evaluation, benchmarking and decision making. In fact they are bar-graph reports that are basically comparative; thus we use statistics, analyses and reports alternately.

Crystal Reports supported by Visual Studio is used in the implementation. Crystal Reports is a business intelligence application used to design and generate reports from a wide range of data sources. Reports prepared with Crystal can easily be exported to Adobe Acrobat Reader (pdf), Text (txt), Excel (xls), Word (doc), HTML (html) formats; and can easily be printed.

Reports are designed to involve a bar-chart on the top, and detailed entries at the bottom. They can only be managed by administrators. For the moment, there are 3 groups of reports: Maintenance Delays, Maintenance Results and Failures.

i. Maintenance Delay group supplies reports of Delay Day - Number: Gives the frequency of delay day count. Delay Person - Number: Gives how many times technical

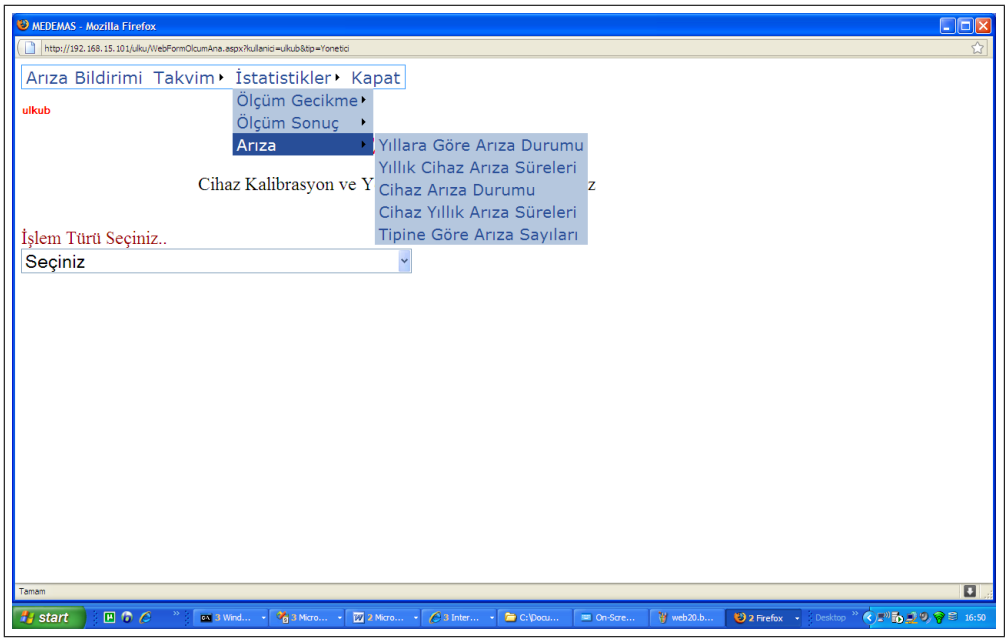

Figure 4.35 Statistics Menu Expanded.

staff delayed their appointments. Delay Person-Day-Number: Gives delay day count statistics of technical staff. Delay Year-Person-Number: Gives delay counts of staffs grouped into years.

ii. Maintenance Results supplies: Device Maintenance Results: Pass/Fail Numbers of Devices are graphed. Failed Maintenances on Year Basis: Pass/Fail numbers of devices are grouped into years.

iii. Failure supplies: Device failure counts on yearly basis: Gives total failure count in a year Device total failure (idle) day count on yearly basis: Gives total idle time in a year Yearly failure count history on device basis: Gives device yearly failure counts Yearly failed duration history on device basis: Gives each device's total idle times grouped into years. Failure counts on failure type basis: Determines the occurrence frequency of failure types. This report is included in Figure 4.36 as an example of Statistics.

These statistics guide the administrators in evaluating performance issues. From the reports, performance of technical staff: their maintenance delays and failed main-

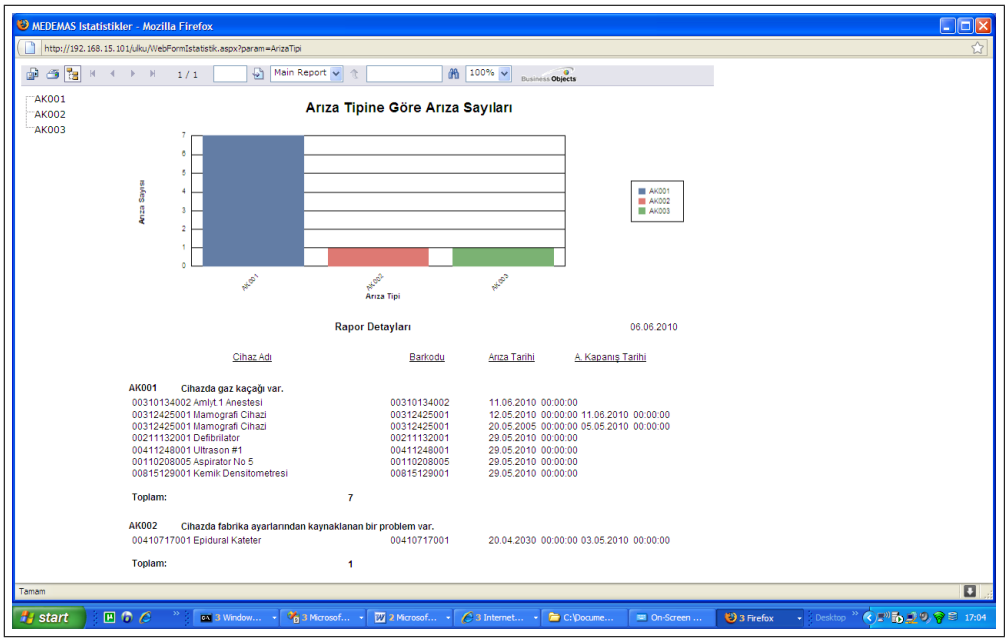

Figure 4.36 Failure Counts on Failure Type Basis Report.

tenances can be observed. Similarly, device performances, in means of their failure frequency and maintenance failure can be followed. Decisions about the staff and devices can be taken.

There are many risk management parameters [23], replacement parameters [24] and benchmarking parameters; thus we plan to expand the reporting facility: both in report variety and report content aspects.

4.2.9 Security and Authentication issues

MEDEMAS operates on user authentication. Initially, user password is given by the operator creating user database entry. Later, only the user himself/herself can change or reset his/her own password. If reset is chosen, a random password is generated and sent to his/her e-mail address. Passwords are protected & kept with md5 encryption. User access level is assigned at the time of user definition and only the operations that level allows can be accessed. This is especially important as the technical staff and ordinary users should not see statistics/reports section, and techni-

cal staff should not see their maintenance operation's results straight after operation completion.

Web application is protected from anonymous access by marking session as logged in at the first window and checking session status in the following windows. Doing so, we block direct access to orphan windows. Default idle session time out is 30 minutes.

4.2.10 Automatic Maintenance Schedule Creation

We followed the current practice of hospitals by planning yearly schedules. We make use of maintenance frequency parameter required from the user at the time of medical device type definition. Yearly maintenance count is calculated with a simple division, and that number of appointments are scheduled consecutively. The first date determined for the next appointment is the current date + frequency month. Following appointment dates are determined with the previous appointment date + frequency month. Whenever a specific date is decided on, whole day is scanned to find a proper time. Working hours (9:00-18:00) are scanned in 30 minute time intervals; sample intervals are 11:00 - (11:00 + device maintenance duration); 11:30- (11:30 + device maintenance duration). For each interval, the parameters checked are, respectively:

- Determining medical device availability: The medical device (patient) appointment database that is imported from hospital database is searched through to see if the device has a patient appointment at that specific time interval.
- Finding an available measurement device of type defined in procedure step definition: Medical Device Umdns is used to reach its procedure definition and all measurement device types indicated in its procedure are brought. For each device type, all measurement devices of that type are searched through to find whether there is any idle device. For each measurement device, we search through measurement device appointments database to check whether the device has any

appointments in between interval start time and interval start + medical device maintenance duration time. Among the available measurement devices, we select the one having least appointment load on that day.

- Finding available technical staff: Technical staff list is checked throughout to see if anyone is available. If found, the person having least appointment load on that day is selected.

The processes above are in complexity order. In order not to cause any redundant work load, the time interval is refreshed whenever the processing step returns "not available". If an available time could not be found for an appointment on that day, the next day is processed and this is done (looped) till a proper time is caught.

As soon as an available device/staff is found, its availability status is marked as unavailable. When the appointment process is over, it is emptied back. A device/staff is regarded as available, in terms of conflict detection, when its availability status is not unavailable or its unavailable for more than 5 minutes.

When an appointment time is decided on, a record for medical device is added in maintenance calendar database and a record is added to appointments of that device in medical device appointments database (to export to hospital database; we do not want any patient appointments just at the time of maintenance). Additionally, records for appointments of the measurement devices selected for access are added in measurement device appointments database.

4.3 Mail Notification Process

Mail notification is a small server-side application that works underneath and is not felt by users. It is a windows service that periodically sends mails to:

- Technical staff to remind their medical device maintenance appointments in

prospect: Sends e-mail once 6 hour starting from 24 hours before the appointment.

- Technical staff to remind their missed medical device maintenance appointments: Sends e-mail to remind missed appointment once a day.
- Administrative staff to inform about medical device maintenance appointments delayed: Sends notification e-mail once a day.
- Technical staff to remind their measurement device maintenance appointments in prospect: Sends e-mail once 6 hour starting from 24 hours before the appointment.
- Technical staff to remind their missed measurement device maintenance appointments: Sends e-mail to remind missed appointment once a day.
- Administrative staff to inform about measurement device maintenance appointments delayed: Sends notification e-mail once a day.

5. DISCUSSION, CONCLUSION and FUTURE WORK

Maintenance and repair are important for patient safety and proper functioning of the medical devices, as they prevent performance decrease of medical devices, deterioration of the equipment, and detrimental effects on the health of the patient, the user or other persons. They are also important in terms of accreditations; in order the hospitals get accreditation, they have to conform to international regulations and standards required.

In this thesis we designed and implemented a medical device maintenance application which fills the gap in practice: offers a standardized, paper-free and remotely accessible device inventory and device maintenance management system.

We derived maintenance procedures from internationally accepted device standards such as ISO, ECRI and AAMI and standardized them so that they were recordable with maximum elasticity.

MEDEMAS is a dynamic maintenance application; procedures, devices, device types and failure types can be added or updated. It successfully leads the technical staff in maintenance process, using the procedures defined. It evaluates the measurements gathered from the user and determines a generic result.

MEDEMAS arranges maintenance appointments automatically, using all medical device, measurement device and staff resources efficiently in terms of work load distribution. Maintenances are made remotely, using -preferably- hand terminals. This means comfort, practicality and easiness for the staff; and immediate data harvesting and fast handling of failures for us. MEDEMAS is a system where we succeeded to make the maintenance process more accurate, more efficient, faster and easier to manage and organize; and much less confusing/disordered.

In this study, we did not deal with financial parameters of medical device management. Especially repair costs are important in benchmarking and device replacement decision. Thus, we plan to integrate financial issues, i.e. maintenance and repair costs to the system.

In fact this integration will be a small part of the bigger integration process: integration with hospital management system. Combining MEDEMAS with device usage information, even patient information will strengthen it. We also plan to unite medical device stock management system with MEDEMAS.

The training of personnel is a key element in safe and effective repair and maintenance work. Health and Safety Law requires employers to ensure their employees are adequately trained. All service personnel need to understand the basic principles on which devices work (generic training) as well as how to use, repair and maintain a particular model (specific training). Both are necessary [25]. Training maintenance, when applied, will empower our study.

Statistical reports are a little behind of what we can do. Reports will be shaped better when there is interaction with a hospital. We aim to improve reports in time. Risk management and benchmarking issues are explained earlier. We also want to automate them to the extent it can be done.

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