ESTABLISHING
BIOMEDICAL EQUIPMENT MAINTENANCE PROGRAMS
FOR HOSPITALS IN TURKEY

by

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ABSTRACT

The function of a hospital is to meet the acute health needs of the community it serves. Biomedical instrumentation maintenance programs have been established to help hospitals meet these needs through the effective use of technology. These programs can be provided by both outside and in-hospital service organizations.

In this study, the elements of an effective biomedical instrumentation maintenance program are presented, and various service options are discussed. In addition, data from surveys carried out in selected hospitals and original equipment manufacturer's representatives in Turkey are provided.

In Turkey, there are fewer engineers and technicians in biomedical engineering discipline than are presently needed. There is only one Biomedical Engineering Institute at Boğaziçi University graduating Biomedical Engineers. Keeping this fact and the findings of the survey in account, 'model' biomedical instrumentation maintenance programs for small, medium-sized and large hospitals in Turkey are developed. A case study related to establishing an in-hospital biomedical engineering department in Şişli Etfal Hospital is also presented.

The proposed 'model' biomedical equipment maintenance programs will help to provide safe, high quality medical care, and effective cost control of this care.

ÖZET

Bir hastanenin işlevi, hizmet verdiği topluluğun sağlık gereksinmelerini karşılamaktır. Hastanelerin bu işlevlerinin gerçeklestirirken teknolojinin getirdiği olanakları doğru ve verimli kullanmalarını sağlamak için tıp cihazları bakım programları geliştirilmiştir. Bu programlar, hastanelerde kurulacak biyomedikal mühendisliği bölümleri tarafından uygulanabileceği gibi, özel kuruluşlarca da gerçekleştirilebilir.

Bu çalışmada, etkin bir tıp cihazları bakım programının bileşenleri sunulmuş ve değişik servis seçenekleri tartışılmıştır. Ek olarak, Türkiye'deki seçilmiş hastanelerde ve tıp cihazları yapımcılarının temsilci firmalarında yapılan araştırma sonuçları verilmiştir.

Türkiye'de halen Biyomedikal Mühendislik alanında gerekenden daha az mühendis ve teknisyen bulunmaktadır. Biyomedikal Mühendisliği mezunu veren yanlız Boğaziçi Üniversitesi Biyomedikal Mühendişliği Enstitüsü vardır. Bu koşullar ve araştırma sonuçları göz önüne alınarak Türkiye'deki küçük, orta ve büyük boyutlu hastaneler için 'model' tıp cihazları bakım programları geliştirilmiştir. Şişli Etfal Hastanesinde bir biyomedikal mühendisliği bölümünün kurulması ile ilgili bir olay incelemesi de sunulmuştur.

Bu çalışmada önerilen 'model' tıp cihazları bakım programları, sağlık hizmetlerinin güvenilir ve kaliteli olmasına ve bu hizmetlerin maliyet kontrollerinin etkili bir biçimde yapılmasına yardımcı olur.

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I.

INTRODUCTION

The function of a hospital is to meet the acute health care needs of the community it serves. In achieving this goal developments in biomedical instrumentation provide a wide range of support.

Biomedical instrumentation in addition to contributing to tremendous benefits and improvements in patient care, has also brought new problems to the hospital. In Turkey they are largely due to the lack of technical understanding of hospital personnel in the operation and utility of this new technology, and inadequate biomedical instrumentation maintenance programs.

An ineffective biomedical equipment control program will result in increased risk to patient and operator, increased hospital liability, noncompliance with regulations and poor cost-effectiveness as described in Figure 1.1. These problems are minimized if an effective equipment control program is available. The benefits of such a program are improved utilization and performance of equipment, minimized risk to the patient and hospital personnel due to equipment malfunction, and improved cost-control.

A biomedical instrumentation maintenance program can be accomplished by one or more of a variety of service options. The decision on what type of program best fulfils

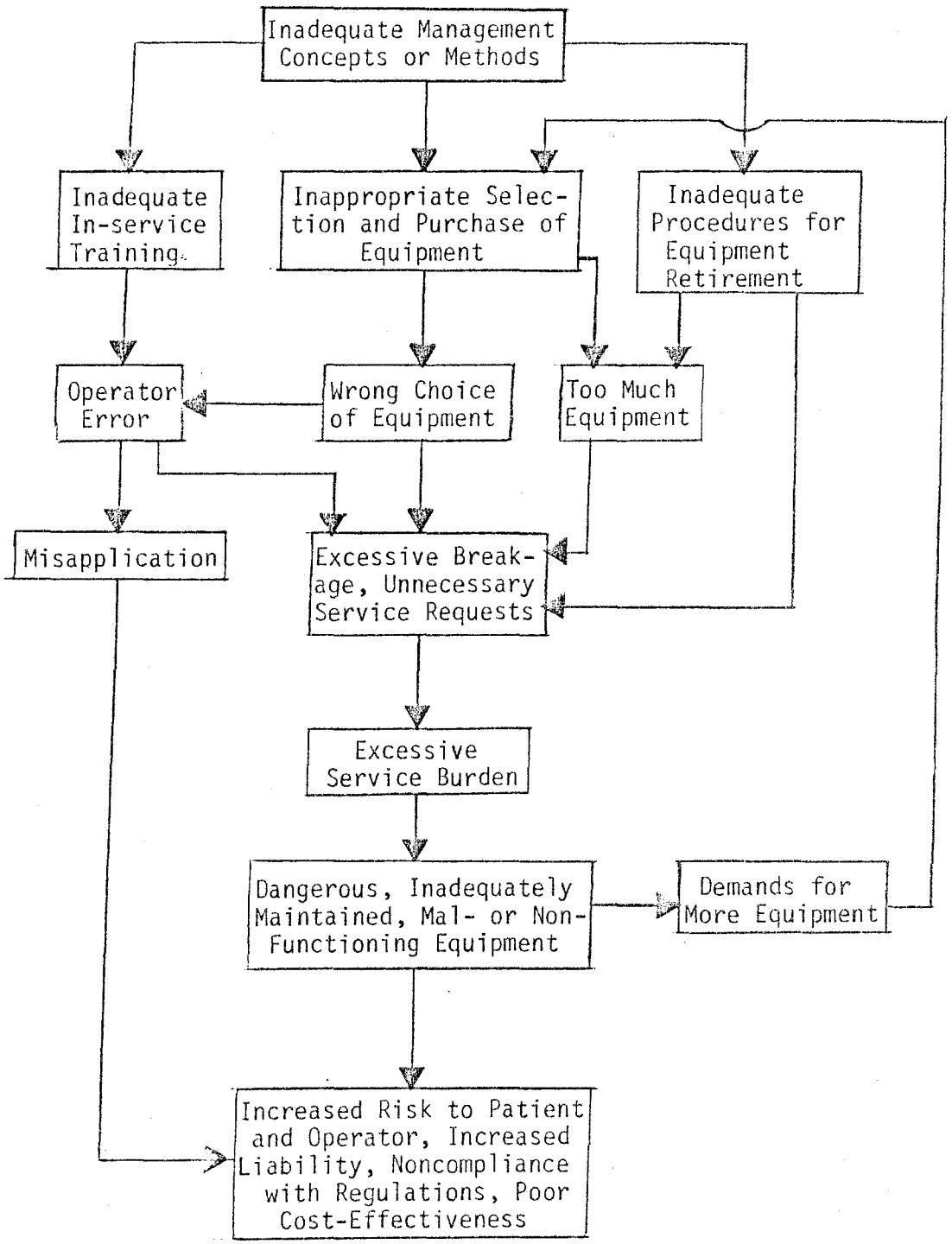


Figure 1.1. Results of an ineffective equipment control program.

the need of any particular hospital depends on many factors. In most cases, a combination of alternatives provides the optimal program.

In this thesis, an overview including the elements of an effective biomedical instrumentation maintenance program and service options will be provided. In addition, the findings of the study of programs currently employed in selected hospitals in Turkey will be presented.Following an analysis of the study, "model" biomedical equipment maintenance programs for hospitals in Turkey will be proposed, and a case study related to establishing an in-hospital biomedical engineering department will be presented.

Following the introduction, the elements of an effective biomedical equipment program will be introduced in Chapter II.

In Chapter III, various service options together with the advantages and disadvantages will be discussed.

The objectives and findings of the study are presented in Chapter IV.

Chapter V covers the proposed "model" biomedical instrumentation maintenance programs for hospitals in Turkey.

In Chapter VI, a case study covering several aspects of establishing an in-hospital biomedical engineering department (including costs) is presented.

II.

BIOMEDICAL INSTRUMENTATION MAINTENANCE PROGRAM: AN OVERVIEW

Biomedical instrumentation maintenance programs have been established to help hospitals provide through technology,safe and high quality medical care. Their purpose is to ensure that appropriate equipment is available in a safe and serviceable condition and at a reasonable cost.

An effective maintenance program will include:

i. Equipment selection,

ii. Acceptance testing,

iii. In-service training,

iv. Equipment service- preventive maintenance and repair,

v. Equipment replacement.

2.1 EQUIPMENT SELECTION

Unless high quality equipment is purchased initially,no amount of subsequent activity will matter. First clinical needs must be defined. Following this, the technical specifications of the devices can be decided upon and alternative sources for providing the equipment evaluated. An advisory

group comprising specialists from engineering, purchasing, biomedical engineering and the clinical users need to evaluate the various alternatives. In doing so, they should consider a number of points including performance, reliability, compatibility, repairability, technical support available from the manufacturer, ease of use, facility requirements, safety, and overall costs.

Table 2.1 represents typical issues to be considered before purchasing biomedical equipment.

2.2 ACCEPTANCE TESTING

All incoming equipment should be inspected for electrical safety and for conformance with the hospital's and manufacturer's performance specifications before being placed into service. This initial inspection should confirm that the equipment is undamaged, safe, all accessories have been provided, and in proper working order. Advisory group members involved in the pre-purchase decision should participate in this acceptance procedure. They should also verify that detailed documentation, including operating and service manuals, have been provided.

Once the instrument has passed the incoming inspection and has been accepted for use, an equipment control number should be assigned and the instrument appropriately tagged.

PRE-PURCHASE EVALUATION QUESTIONS
1.Is it properly designed?
2.Is it easy to repair?
3.Does it meet functional expectations?
4.Is it electrically and mechanically safe?
5.Are spare parts to be stocked?
6.Does it require special wiring?
7.Does it meet all standars and codes?
8.Are there manuals and schematics available?
9.Is training required?

Table 2.1 Pre-purchase Evaluation Questions.

A control record should be prepared, catalogued and filed. These procedures should be followed by a formal commissioning session including a demonstration and a period of training for clinical and biomedical engineering personnel covering both operating and service details.

2.3 IN-SERVICE TRAINING

No new equipment should be placed into service until appropriate clinical personnel have had adequate training in

its use, servicing and emergency action in the event of malfunction. Those unfamiliar with the equipment should be forbidden to operate it unless supervised or until they are certified in its use.

In-service training may be provided by the technical service representatives or by the manufacturers representatives. Proper training of medical personnel decreases the incidence of operator error and misapplication of equipment, which in turn decreases risk to patient, and reduces the number of device malfunctions due to misuse or abuse of equipment. Service calls that involve user errors are time consuming and very costly. Proper user education represents an important saving.

2.4 EQUIPMENT SERVICE

If equipment is to remain safe, servicable and reliable, a formal system of maintenance is essential. This includes regular safety inspections, calibration, and routine preventive maintenance on a planned and controlled basis. The program should include:

- comprehensive safety inspections,
- thorough lubrication where appropriate,
- calibration,
- performance tests,

- final functional check.

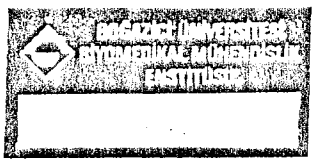
A record of these inspections should be maintained for each device and maintained in a permanant file. These records provide a means of assessing replacement needs and the equipments' cost effectiveness.

Following the preventive maintenance and inspection, a tag should be placed on the device indicating the results of the inspection. For example, a ground warning tag may be placed if electrical leakage current exceeds safe limits.

If the scheduled preventive maintenance system is operating properly, breakdowns should be relatively infrequent. However,even the most comprehensive program cannot eliminate random failure. An effective emergency repair program should be implemented to ensure that such breakdowns are dealt with immediately and effectively. This includes an adequate inventory of spare parts that require frequent replacement and having adequately trained personnel available to perform repair.

Before requesting service for a defective device, a 'defective do not use' tag should be placed on the equipment by clinical personnel to avoid any hazards to patient or operator. Figure 2.1 represents various equipment tags.

Reports summerizing service calls and repairs should be maintained. These are useful in evaluating the need to replace equipment with more reliable devices.



CONTROL NUMBER

INSPECTED BY

DATE

CAUTION

This device recently underwent inspection and preventive maintenance. Please check the position and setting of controls, valves, alarms, and indicators since they may have been changed from their previous positions. Check vaporizer levels and all patient circuit components, including valves and connectors, for proper operation and safety. Please remove this tag upon first post-inspection clinical use.

BY _____ Date _____

DANGER

DEFECTIVE

DO NOT USE

DO NOT REMOVE THIS LABEL

DATE _____

NAME _____

Figure 2.1. Examples of various equipment tags.

2.5 EQUIPMENT REPLACEMENT

Equipment may have to be replaced for one ore more of the following reasons:

- Worn out beyond repair,
- Damaged beyond repair,
- Unreliable,
- Clinically or technically obsolete,
- Spare parts no longer available.

No matter who makes the request for replacement- the user department or servicing group- it is necessary to document the need for replacement, to allow adequate time to arrange for appropriate budget allocations and to select the replacement device wisely. Hurried or unstructured purchase of replacement equipment should be avoided because it inevitably leads to poor cost effectiveness.

III.

OPTIONS FOR MEDICAL INSTRUMENTATION MAINTENANCE

The maintenance of medical instrumentation in hospitals can be provided by both outside and in-hospital service organizations. The decision on what type of program best fulfils the need of any particular hospital depends on many factors. They include size, location, and type of hospital. In most cases, a conbination of alternatives provides the optimal program. These alternatives are:

i. Original Equipment Manufacturer,

ii. Department Engineers and Technicians,

iii. Plant Engineers or Electricians,

iv. Shared Biomedical Engineering Services,

v. In-hospital Biomedical Engineering Department.

3.1 ORIGINAL EQUIPMENT MANUFACTURER

3.1.1 Responsibilities

The original equipment manufacturer is expected to provide instrumentation of high quality, in accordance with good manufacturing practices and meeting legal, ethical, and safety requirements. In addition, the manufacturer has the responsibility to assure the proper care, and safe and

effective use of the medical equipment. Therefore complete and detailed documentation and support are usually available. The documentation is thorough enough to enable trained personnel to provide appropriate preventive maintenance and repair services.

3.1.1.1 Documentation

Complete and easy to understand documentation is required for the proper use and support of medical instrumentation. Although the specific level of documentation needed varies with the complexity of the instrument, general documentation requirements for all instruments include the following information:

- detailed technical specifications,
- full operating, service, and troubleshooting instructions,
- detailed parts listing,
- appropriate schematics,
- a statement of warranty.

Technical specifications should be written so that trained personnel can easily understand safety, performance and repair details. Operating instructions should provide the device user with specific, detailed information on the function and operation of the instrument or system.

Service manuals should provide well information necessary for the inspection, calibration, repair, and maintenance of

the instrument or system.

A written warranty should be provided and should include the length and exceptions to the warranty.

Additional information may include installation instructions, inspection criteria and expected results, licenses, releases, and patent information.

3.1.1.2 User Support

The user should be adequately supported in the maintenance and operation of medical devices by appropriate educational and training services provided by the manufacturer. These services may entail special fees over and above the cost of the equipment, including trips to special training centers or the manufacturing facility where special in-service resources are available.

The user should be assisted with routine applications of the equipment by continuing in-service education and by offering periodic continuing technical training covering new applications and advanced theory of operation of the equipment. The manufacturer also should assume providing the responsibility for maintenance and repair services. Either the manufacturer or an authorized representative should offer field service for all nonportable instruments as well as factory repair services for small or portable instruments easily shipped. They should also provide the parts necessary to maintain or repair equipment throughout its useful life.

Service contracts should be offered for manufacturer-authorized repair and maintenance. These contracts should cover, as a minimum, at least one preventive maintenance inspection per year; repair of any malfunction which degrades performance or safety ; and documentation to meet regulatory requirements applicable to the end user. A statement of on-site response time and average repair time, a description of the qualifications of service personnel, and a statement on the availability of backup equipment should also be included in the service contract.

In addition to the documentation and user support requirements, the manufacturer must maintain a system for providing users with updates, modifications, software releases, hazard notices, and recalls.

3.1.2 Service Provided by the Original Equipment Manufacturer

Original equipment manufacturers or their service representatives usually provide repair and maintenance services only for the equipment that they manufacture and sell. There are large variations in the type, quality, and availability of support offered because of similar large variations in the size of manufacturers and in the quality of their products.

Services may be purchased under a fixed-price contract, providing a quaranteed form of cost control, or on a per-call

time and material basis.

If manufacturer's or their representative's repair and service contracts are to be considered, the following advantages and disadvantages should be examined.

3.1.2.1 Advantages

The main advantage of original equipment manufacturer service is that their service representatives are usually highly qualified and have specialized training in the specific equipment that they service. This enables them to efficiently service equipment with a minimum of downtime. They are responsible for only one or a limited class of devices and can thus concentrate their efforts more efficiently. Original equipment manufacturer service has clear advantages for specialized, highly complex or one-of-a-kind medical devices.

The manufacturer can more readily identify recurring problems. This service option can also lead to quicker instrumentation field updates and manufacturer modifications.

Another advantage is that for smaller non-installed equipment, a manufacturer's representative may have loaner units available while the hospital owned equipment is being repaired.

3.1.2.2 Disadvantages

The disadvantages are higher costs, slower response time and fragmentation.

The original equipment manufacturer service is typically expensive, with hospitals usually paying an hourly charge for service calls on a 'portal to portal' basis and for parts which have a high mark-up. It is common for hospitals to pay exorbitant prices for parts that are part of lower-cost service contracts in which parts are 'extra'.

The slower response time is attributed both to travel time and commitments to other customers. First there is the delay waiting for the serviceman to arrive. Then there might be more time lost if he does not have a necessary part with him, of if he does not have adequate test equipment and proper tools to deal with the specific problem diagnosis. If, as is often the case in a hospital, a 'repair' is a matter of correcting user error, equipment will be taken out of service unnecessarily, to await the arrival of the serviceman. When he arrives, he may find nothing wrong with the equipment, and the hospital is forced to pay for a service call.

Total dependence on manufacturer's service representatives leads to fragmentation of the overall program because they will service only the equipment they sell.

There is also the matter of 'loaners'. Many manufacturers promise immediate loaners while equipment is being repaired. However, loaners have been known to take weeks to arrive,

and many of them are defective upon arrival. If the unit in question is not replaced by exactly the same unit, the user may be unfamiliar with it, and patient care will be compromised especially if the item is a critical device like a defibrillator or a respirator.

3.2 PLANT ENGINEERS AND TECHNICIANS

In-hospital plant engineers and electricians, traditionally, have been responsible for building systems and operations including heating, air conditioning, electrical power distribution, and fire safety. These men have very limited knowledge of highly technical and complex medical instrumentation since they have no biomedical engineering education nor are they equipped to work in this specialized discipline, which requires significant clinical knowledge. Placing medical device problems in addition to the routine plant maintenance on these engineers is unfair both to these men and to the hospital patients.

As a consequence placing biomedical engineering under the existing plant engineering department is usually an ineffective arrangement. The differences in experience, attitude, professional goals, and motivation between plant engineering personnel and biomedical engineering personnel often causes problems in scheduling, in assigning priorities,

and in budgetary matters. There is one exception however. If the chief plant enginner is also a biomedical engineer, then it is possible that the biomedical engineering group will function well under the management of plant engineering.

3.3 DEPARTMENTAL ENGINEERS AND TECHNICIANS

Some hospitals, especially teaching ones, have encouraged individual medical departments- such as surgery, anesthesiology and cardiology- to hire their own engineers or technicians. Unfortunately they usually spend their time on the 'pet projects' of one or two influential members of the department. This limits their ability to provide the broad spectrum of technical services required such as evaluation, testing and repair of all the departments devices.

Another negative aspect of this arrangement is the spoken or unspoken competition or jealousy between medical departments. Many departments with their own technician will limit his availability to other departments, even though he has the appropriate skills to provide a useful service to them. There will be a minimum of cooperation in the scheduling of his technical services to other areas of the hospital.

As a consequence, other medical units will hire their own technicians. This leads to duplication of tasks, supplies, space, and costs. Because skilled biomedical engineers and

technicians are scarce resources, this approach is a disservice to the entire health care system.

3.4 SHARED SERVICES

In a shared services arrangement, a nonprofit or profit organization is involved in servicing a large number of hospitals in one geographical area. These organizations provide technical services such as repair, preventive maintenance, and engineering consultation. The member hospitals of the shared service usually pay for services in proportion to their use, and the inital capital costs are shared among the user facilities.

The shared service concept has merit for those hospitals which cannot afford a full in-hospital capability. When considering such an arrangement the following advantages and disadvantages should be examined.

3.4.1 Advantages

The main advantages are decreased cost, speed and efficiency of service, and a broad technical base of support.

The costs of establishing a maintenance service are distributed to all hospitals, and the member hospitals usually retain a representative share of the management control and

development of the program, so start-up costs are reasonable. In addition, not having to send equipment out for repair eliminates the cost of transportation.

Response time is usually good when user facilities are close together.

Since shared services organizations provide a wide range of services- like equipment information record keeping, incoming inspection, accidents investigation- maintenance costs and the fragmentation of the hospital's overall equipment control program is reduced. Some of these organizations also offer equipment procurement and engineering consultant services.

3.4.2 Disadvantages

Shared service organization groups usually are not hospital based. There are no in-hospital personnel involved, so immediate assistance and on-the-spot emergency repairs cannot be provided.

An excessive number of personnel would be required in order for a single group to do a proper job in many hospitals at the same time. If the organization is not hospital based, then there may be lack of close supervision of personnel.

3.5 IN-HOSPITAL BIOMEDICAL ENGINEERING DEPARTMENT

An in-hospital biomedical engineering department can provide a full range of services including initial equipment checkout, preventive maintenance, repair, inventory control, inservice training, cost containment, risk management, pre-purchase evaluation, and engineering design services. The development and implementation of an effective medical instrumentation maintenance program including the above services requires the cooperation of all departments within the hospital. The responsibilities of all personnel must be clearly understood.

3.5.1 Responsibilities of Hospital Personnel

Administration should provide adequate work space, personnel, test equipment, and supplies to enable biomedical engineering to accomplish its specified objectives. The hospital's administration must also provide strong backing and support to the technical group which will help the group gain the acceptance, cooperation, and ultimately, the respect of medical and nursing personnel. This is important because the medical personnel's formal education placed very little emphasis on mathematics, physics, or engineering, so they usually have an inadequate understanding, not only of complex instrumentation, but also of engineers and engineering technicians.

The medical personnel are responsible for the safe and proper operation of medical equipment in use within the hospital. They should participate in the clinical evaluation of the devices before purchasing new equipment, and should report malfunctions as they occur to the biomedical engineering. In conjunction with the department,they should conduct inservice training programs to ensure the proper operation and application of the patient-related equipment.

The purchasing and accounting department should provide current information regarding the prices, availability, and alternate sources of supply when a new device is going to be purchased. They should consider several purchasing criteria together with the biomedical engineering, user department, and administration before making the purchasing decision. They should ensure the delivery of the newly-purchased instrumentation to the biomedical engineering department for acceptance test. It is also their responsibility to contact the outside service companies if a service contract is going to be signed.

The maintenance and plant engineering department staff should participate in evaluation of equipment requirements for installation and renovation, considering the physical plant requirements.

3.5.2 Responsibilities and Organization of the Biomedical Engineering Department

A centralized in-hospital biomedical engineering department can provide a wide variety of services as follows:

- evaluation of new instrumentation on the market,
- review of all medical device purchase requisitions,
- acceptance testing of all newly-purchased hospital instrumentation,
- repair of all broken or malfunctioning equipment,
- preventive maintenance of hospital equipment,
- patient montioring during major surgery,
- design and construction of specialized instrumentation for clinicians and researchers,
- educating medical personnel in the selection, use and care of medical instrumentation.

In order for an in-hospital biomedical engineering group to adequately provide the above services, the size of its staff and facilities must be dictated by the number of the beds and by the amount and types of instrumentation. However, a typical organization structure illustrated in Figure 3.1 is common to all in-hospital biomedical engineering departments.

The group should be headed by an engineer who is responsible for pre-purchase evaluation of the complete

biomedical engineering program. The director of the department is responsible only to the hospital's administration.

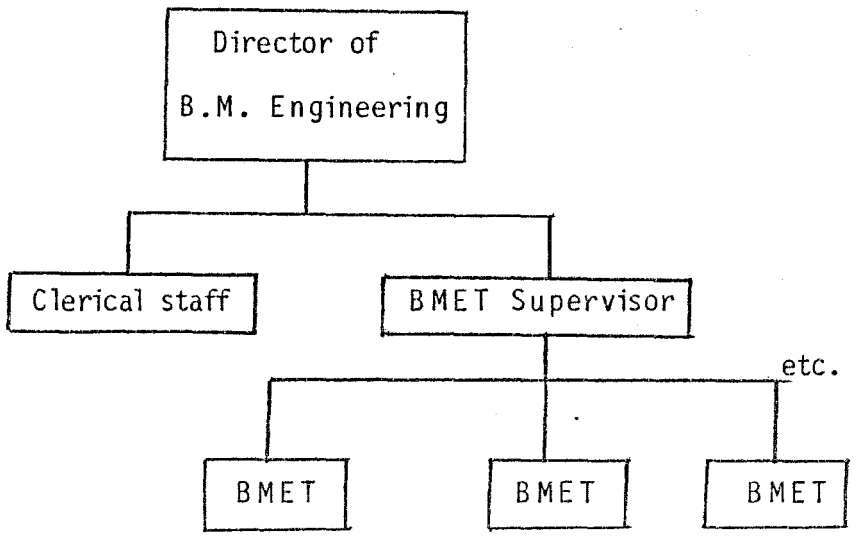


Figure 3.1 Typical Organizational Structure of an In-hospital Biomedical Engineering Department.

The supervisor of the biomedical equipment technicians (BMET) can be an electrical or biomedical engineer, or an experienced BMET who is responsible for scheduling work and inspections to be performed,and for communicating with medical staff and equipment vendors.

BMETs are a most valuable component of a successful biomedical engineering program. They provide the majority of the repair, maintenance, calibration, and inspection service.

Electronics technicians can also provide effective repair services for the hospital if properly supervised and trained.

3.5.2.1 Advantages

The in-hospital program offers significant advantages including total hospital control and centralization of responsibility for equipment maintenance, short response times, improved safety and reduced sources of service. These advantages lead to increased equipment life expectancy, in some cases lower costs than other service arrangements, reduced fragmentation of the hospital's equipment control program, and better quality care.

3.5.2.2 Disadvantages

One of the main disadvantages of the program is significant start-up cost. This initial expense is necessary for test equipment, facilities and salaries. A commitment of time and money are necessary to develoy the program.

In addition, the personnel will not be as specialized as original equipment manufacturers service representatives unless specialized skills are developed.

IV.

STUDY OF PRESENT CONDITIONS AND FINDINGS

4.1 OBJECTIVES

Before proposing an effective and efficient "model" medical instrumentation maintenance program for hospitals in Turkey, the programs currently employed were studied. This study was an overview, intended to uncover and analyze problems and deficiencies in the programs which are in use today. Considering these problems, deficiencies, and resources will allow the proposed model to be more realistic and applicable.

In order to gather as much information as possible about the medical instrumentation maintenance programs and available service options two questionaires were prepared.

The first questionaire was for hospitals and was composed of questions arranged in seven sections. They included equipment selection, purchasing, acceptance, inspection, calibration, repair, in-service training, hazard control and documentation. The questions were answered by hospital personnel who were able to give complete information. If a single person was not able to answer all questions, the missing answers were obtained from someone else. Their alternative solutions for a more complete and effective main-

tenance program are included in the last section of the questionaire.

The hospitals in Turkey are catagorized into five groups including:

i. University Hospitals,

ii. Ministry of Health and Social Welfare(SSYB) Hospitals,

iii. Social Security Administration (SSK) Hospitals,

iv. Private Hospitals,

v. State Economic Enterprise (KIT) Hospitals.

The hospitals selected to participate in this study were from each five types.

A second questionaire was prepared for representatives of medical equipment manufacturers. The questionaire was divided into three sections. They included documentation, service, and in-service training. The five companies selected to participate in the study were representative of the manufacturers who dominate the market in Turkey. The questions were answered by the heads of the service divisions of these companies.

Appendix A includes the questionaires, examples from data, and names of the hospitals and medical equipment manufacturer's representatives participated in this study.

4.2 FINDINGS

The following sections summarize the findings of the survey.

4.2.1 Technical Personnel

i. Most of the technical personnel in hospitals work in the plant engineering department. There were no biomedical engineers or biomedical engineering technicians among them.

ii. Most of the technical personnel are primary or secondary school graduates. Few of them are technical high school or university graduates. For example, in one of the hospitals (with more than 1200 patient beds) there were 59 technical personnel. Among them there were only two university graduates and two technical school graduates, the rest being the graduates of primary or secondary schools.They have no specific formal training in hospital biomedical engineering and medical equipment servicing.

iii. Since the technical personnel are not specialized in medical instrumentation and most of them are not university trained, their salaries are not high, varying from 25,000 TL to 70,000 TL. They generally work eight hours a day and perform simple repairs within

their skills, and report other malfunctions to their supervisors. They spend most of their time maintaining building systems and operations. This would include heating, electrical power distribution, and other plant engineering functions.

iv. In some hospitals technical personnel are supervised by a physicist, an electrical or mechanical engineer. Although they had no formal training and exposure to medical equipment or the unique characteristics of the patient care environment, since their academic exposure facilitates easy adaptation, they are trying to accomplish the objectives of biomedical instrumentation maintenance programs as far as the conditions and regulations allow. They are responsible to the chief of the medical staff.

4.2.2 Selection, Purchasing, and Acceptance

i. Pre-purchase evaluation including the study of clinical needs and the important attributes of the device or system before selection for use in the hospital is performed in some hospitals only by the users, and in the others by a group made up of users and technical personnel.

ii. After the decision for purchasing a device is made,a commission prepares the purchasing specifications.

They also carry out the detailed investigation for selection of the proper device among the ones available in the market.

iii. Usually the commission offer an advisory selection, and the final decision is made in accordance to the advice either by the dean of the university hospitals or by special purchasing committes in the others.

iv. With the exception of private hospitals, questionaire prepared by DPT (Devlet Planlama Teşkilatı) for pre-purchase evaluation and purchase specifications is being used.

v. Acceptance tests are performed in only some of the hospitals. Usually the users check the performance of the device, and technical personnel check whether the performance specifications of the unit meet the manufacturer's design specifications.

vi. When a device is purchased, in most cases, the hospital is not provided with the required documentation in adequate amounts. However, if available, the technical literature is kept either in a central library, or in the user departments.

4.2.3 Inspection, Calibration, Repair

i. In most of the hospitals there is no formal system of safety inspections, calibration and routine preventive

maintenance for their clinical devices. In one hospital, only a single device out of 400 is maintained according to procedures prepared by the manufacturer. In the other hospitals either the department head or one of the technicians are involved in servicing some of the instruments. However, they don't follow a routine procedure. It seems that, although some of them have the necessary test equipment and working space, the importance of routine inspection, calibration, and maintenance is not well understood, and necessary procedures are not developed.

ii. Because of the lack of knowledge and experience in servicing medical devices, technical personnel are not able to perform routine instrument repair. They call the manufacturer representatives in most cases. The response of these service groups vary, but it is usually poor. These services are purchased by hospitals either on a per-call basis (varying from 5,000TL to 11,000 TL), or depending on the complexity of the repair and device.

iii. There are few examples of yearly fixed-price service contracts. Usually, if such a contract is signed, the responsiveness of the representatives emergency service depends on the location of the hospital and number of service personnel available in the company at that moment. In these contracts response time is

usually quaranteed, but may not be followed in practice. If the manufacturer's representative has loaner units available, these can be used in the hospital while the hospital owned equipment is being repaired.For most of the hospitals, their maintenance budget is a limiting factor for signing such contracts.

iv. Some of the hospitals that have routine inspection programs rarely maintain up to date records. Occasionally, some of these records are analyzed by the chief of the medical staff. There is one example where the documentation system is computerized, but in the others it is done manually.

v. In most of the hospitals tagging of unsafe equipments is not available.

4.2.4 Hazard Control and Recalls

Except for the procedures in case of fire, there is no hazard control and recall procedures for accidents that result from equipment malfunction or electrical accidents. In some of the hospitals, there are coordinators to organize the activities only in case of fire.

4.2.5 In-Service Training

i. Most of the in-service training is provided by the manufacturer's representatives including proper use and care of the device. For specialized, highly complex and one-of-a-kind medical devices, the users may be sent to training centers in other countries, or experts from the manufacturer provide training on site. However, staff properly trained in use of medical equipment frequently moves to other posts, and their places are taken by those who may not have seen or operated the apparatus before. Continuing in-service training is usually not sufficient.

ii. Only in two of the hospitals surveyed, training related to safety and electrical accidents were available.

V.

"MODEL" BIOMEDICAL INSTRUMENTATION MAINTENANCE PROGRAMS FOR HOSPITALS IN TURKEY

5.1 GENERAL CONSIDERATIONS

The hospitals in Turkey can be classified into five groups. Because of wide variations in cost considerations, regional requirements, hospital size and available expertise between these groups, it is not possible to define a medical instrumentaion maintenance program that is suitable for all hospitals. However, if hospitals are categorized by size,model programs can be developed. For purposes of this section, a "small" hospital is defined as one having 1 to 25 beds, a "medium-sized" hospital has 25 to 100 beds, and a "large" hospital is one having more than 100 beds.

There are some considerations that apply to all hospitals irrespective of which program options are selected:

i. It is very important that only one person or department serve as the central contact for medical instrumentation maintenance services, and ensure that required inspection and preventive maintenance activities are carried out on a timely basis for the hospital's biomedical equipment.

ii. Regardless of which option, inspection, preventive main-

tenance, and repair activities are performed, a centralized documentation center for these activities should be created. When service contractors complete inspection preventive maintenance activities, they should be required to submit copies of their inspection and preventive maintenance protocols along with detailed documentation of the results of their activities to the documentation center in the hospital. Inspection and equipment control forms described in Appendix B can be used. Also, other documentation including hazard and recall information with follow-up activities should be provided.

iii. Pre-purchase evaluation procedures should be developed and followed by a team made up of users and technical personnel. Consideration should be given to the formal standardisation of certain types of equipment which will enable user training and equipment servicing to be easier and faster. Incoming inspection and acceptance tests should be performed, and records of these activities should be provided.

iv. Availability of repair parts is a problem in Turkey. To solve this, either manufacturer's representatives or hospitals should stock extra parts to be used for emergency repairs. Otherwise in Turkey it generally takes a long time to order to and receive parts from original equipment manufacturers. If a service contract is signed, a clause covering this problem should be included.

v. In-service training activities related to biomedical equipment should be arranged by the hospital. The equipment manufacturer's representatives should provide user training. These activities should be extended to all shifts and made for repetative sessions for replacement staff to receive adequate training.

In addition to the user training, if there are available technical personnel, adequate service training should be provided to perform simple or emergency repair. These personnel should not be permitted to work on medical equipment unless they have adequate training and documentation.

If possible, introducing information about possible electrical accidents and equipment hazards, and precautions will allow the medical personnel to use the instruments safely.

5.2 PROGRAMS FOR HOSPITALS OF VARIOUS SIZES

The following models are related to the size of the hospital. These models can be further adapted to individual hospitals depending on financial resources, physical location with respect to available contractor services, availability of shared services, equipment density, and type of care provided. No matter which service organization is responsible for

equipment maintenance, the functions explained in Chapter II should be performed.

5.2.1 Small Hospitals

In a small hospital, it is not economical to establish a biomedical engineering department because of high start-up costs. Instead, a biomedical equipment technician who is responsible to the chief of medical staff can be hired. Figure 5.1 illustrates the organizational structure for an in-hospital biomedical engineering department in small hospitals.

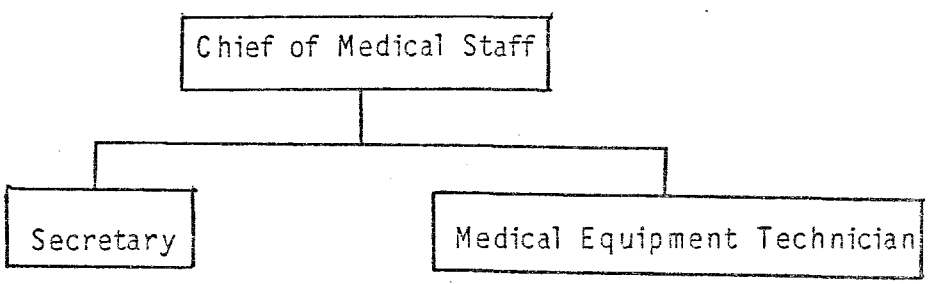


Figure 5.1 Organizational Structure for an In-hospital Biomedical Engineering Department in Small Hospitals.

The medical equipment technician is more likely to be an electrician or other maintenance staff with some training in electrical safety testing. He should report to the chief of medical staff. Together with the secretary he would be responsible for maintaining the documentation.

For servicing medical equipment, the best alternative for small hospitals is shared service organizations. Although such organizations are not widely established in Turkey, some universities have the potential to develop such services. By allowing such organizations to service hospital's biomedical equipment, effective maintenance programs can be ebtablished.

Since the hospital does not have to worry about the personnel and test equipment, the initial costs will not be high. For complex and one-of-a-kind devices contracts should be signed with the manufacturer's representatives.

For such combinations, the most important thing is the coordination. The medical equipment technician hired by the hospital should ensure that equipment maintenance program is accomplished by the responsible organizations. He should try to participate in the training programs, and also perform simple repair.

5.2.2 Medium-Sized Hospitals

In a medium-sized hospital, a small in-hospital biomedical engineering group can be established.The organizational structure is illustrated in Figure 5.2.

The technical supervisor can be an engineer, or a qualified and experienced technician with a general knowledge of medical instrumentation. He should be respons-

ible for establishing an effective biomedical instrumentation maintenance program. For this purpose, he should provide advice on service contracts with manufacturer's representatives and available shared services. He should ensure that documentation of equipment service is maintained. He should be responsible to the chief of medical staff.

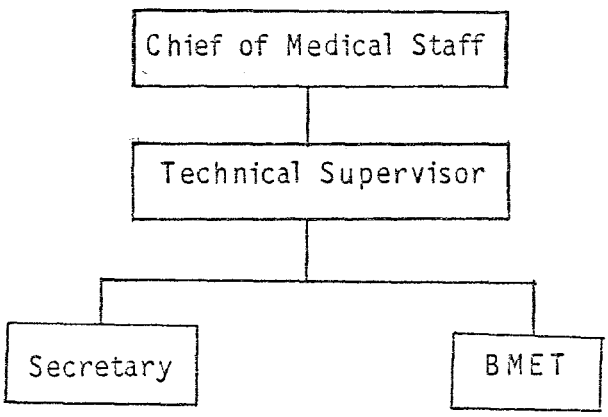


Figure 5.2 The Organizational Structure for a Biomedical Engineering Group in a Medium-sized Hospital.

The sophistication and complexity of equipment in the hospital would dictate the number of BMETs employed. These people, generally are electronic technicians but because of continued exposure to the medical environment evolve into biomedical equipment technicians over time. When these people are hired, they should be paid sufficiently since they are valuable and few in number. The BMET should be allowed to concentrate primarily on biomedical equipment maintenance

and repair under proper supervision.

5.2.3 Large Hospitals

A centralized, in-hospital biomedical engineering department is the best alternative for large hospitals. In order for such a deparment to function effectively, the size of its staff and facilities must be dictated by the size of the hospital and by the amount and types of instrumentation. However, the organizational chart illustrated in Figure 5.3 gives a typical structure and allows for growth and advancement.

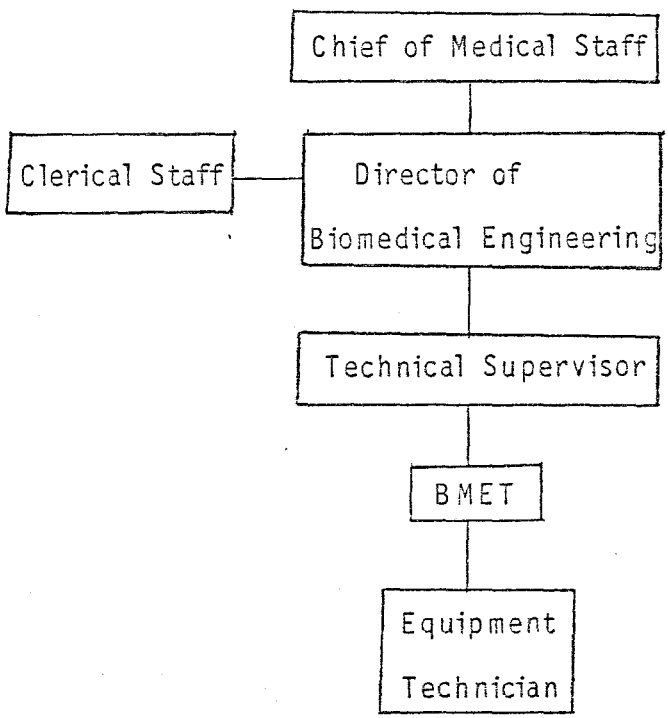


Figure 5.3 A Typical Organizational Structure for Biomedical Engineering Department in Large Hospitals.

The director of the biomedical engineering department should be an engineer, preferably a biomedical engineer. Trained in a broad spectrum of engineering disciplines, management, medical instrumentation and physiology,biomedical engineers can quickly adapt to hospitals and succesfully accomplish the objectives. They should have good relations with medical personnel which will help the biomedical engineering group to gain acceptance, cooperation, and respect of the medical staff. The director of biomedical engineering group must report directly to the chief of medical staff.

Technical supervisors must be engineers.They must have had adequate training and exposure to medical instrumentation so that they can properly supervise the technicians . If they are experts in some special fields of instrumentation, they can supervise the BMET and equipment technicians in the maintenance of that special instrument. Instead of having technicians with a little knowledge about everything, the department will have specialized personnel.Also, it is not economical to train every technician in the care of every device found in the hospital.

Maintaining adequate documentation is the responsibility of the clerical staff. They should ensure that the records of outside service groups reaches the department.

For complex and one-of-a-kind devices, service can be requested from manufacturer's representatives. Initially the best approach is to sign annual service contracts instead of paying time and material charges on a per-call basis.

VI.

CASE STUDY

In the previous chapters the objectives and elements of the biomedical instrumentation maintenance programs, the alternatives to provide these programs, and model programs for small, medium-sized, and large hospitals in Turkey are presented. This chapter introduces several aspects of an inhospital biomedical engineering department, including costs, that can be established in Şişli Etfal Hospital.

Şişli Etfal Hospital is a large hospital with 746 patient beds. It is supported by the Ministry of Health and Social Welfare, and has 22 departments offering service to the patients. There are approximately 118 different types (making a total of 440 in number) of biomedical devices, instruments, and systems available for patient care in the hospital. A list of the devices in each user department is given in Appendix C.

6.1 ORGANIZATION AND RESPONSIBILITIES

In general the staff members should be responsible in accomplishing the objectives of an effective biomedical instrumentation program as introduced in Chapter II. To

achieve this goal, the department should have the organization illustrated in Figure 6.1, and for each member detailed job descriptions should be developed.

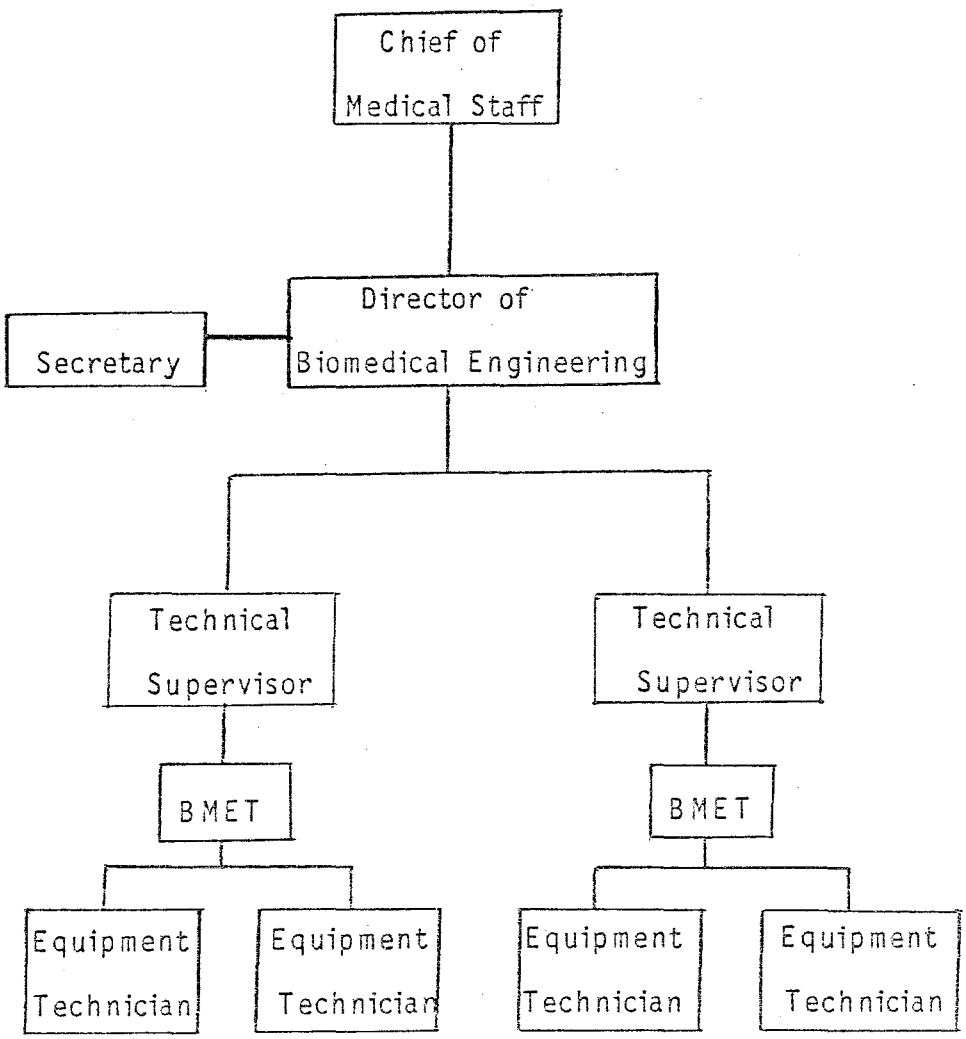


Figure 6.1 Organizational Chart of the In-hospital Biomedical Engineering Department for Şişli Etfal Hospital.

The director of the department should be a biomedical engineer being responsible in departmental administration, procedural decisions, pre-purchase evaluation, and overall management functions.

A secretary should provide work orders to the members of the department and maintain adequate documentation of maintenance.

The two technical supervisors should be engineers with adequate training and experience in biomedical istrumentation. They must be responsible for scheduling work and inspections to be performed, additional duties include communication with medical staff, equipment vendors, and outside service organizations.

The BMETs must provide the majority of the repair, calibration and inspection service. They must supervise the equipment technicians and provide training for them. One of the equipment technicians should receive special training in mechanical repairs. The rest should mainly perform electronic repairs in addition to mechanical repairs. There should be some overlap in the training and skills of the technicians so that repair and maintenance services can be adequately covered in the event of illness, vacation, or other absences of individual staff members.

The average annual salaries of these staff members are given below:

	(in TL)
Director	1,800,000
Secretary	840,000
Two Technical Supervisors	2,160,000
Two BMETs	1,680,000
Four Equipment Technicians	2,880,000
TOTAL	9,360,000

6.2 SPACE REQUIREMENTS

Adequate space must be available for administrative functions, for electronics shop and for a mechanical shop.

A minimum of 12 square meter of administrative space for the director of BME, and 6 square meter of space for each technical supervisors and secretary should be provided

A 6 square meter space is also needed to house the computer system (which will be used for documentation), biomedical equipment library (operator and service manuals etc.), and maintenance files.

A 14 square meter space should be available for electronic shop. Each BMET and Equipment technician will then have more than 2 square meter area work space if they perform

repairs at the same time, which is usually not the case.

A mechanical shop, 14 square meter, should be available to accommodate large pieces of equipment such as beds, operating tables etc., and to house and safely operate a variety of nonportable machine shop tools (milling machines, grinders, welders etc.).

For consumables and spare parts a small storage room of 6 square meter should be available.

The necessary changes and additional construction in the present hospital building, and required office furniture (tables, chairs, carpets etc.)will cost approximately 1 million TL.

6.3 TEST EQUIPMENT

The following list of test equipments is prepared by taking into acount the number and types of devices, and their probability of requiring repair at the same time. These devices are categorized by area of application within the hospital. Some items are not specific and can be used in many different areas of application, otheras have a single function and are used for only one specific task.

i. All patient care areas: 2 electrical safety analyzers, 1 defibrillator tester, 1 ac outlet polarity tester.

ii. Intensive care units: 1 ECG calibrator, 1 respiration and temperature simulators, 2 stop watch, 3 mercury manometer.

iii. Respiratory therapy/pulmonary function unit: 1 test lung, 1 oxygen analyzer, 1 flowmeter.

iv. Neonatal unit: 4 thermometer, 1 lightmeter.

v. Surgery: 2 electrosurgical unit tester.

vi. Radiology: 1 radiation level detector.

vii. Clinical laboratory: 2 stroboscope.

viii. General purpose electronic test equipment: 1 oscilloscope, 1 signal generator, 1 voltage-controlled ac power source, 1 isolation transformer, 1 ammeter, 1 resistor and capacitor box.

The overall costs of these test equipments including some mechanical tools will be around 4 million TL.

6.4 SPARE PARTS

For biomedical devices that are going to be purchased, an agreement should be made between the buyer and the seller in order to guarantee the availability of spare parts when needed. If service contracts are signed for complex, one-of-a-kind devices, the servicing organization should guarantee the support of spare parts in certain time limitations.

The hospital should consider a cost of spare parts approximately as 10 percent of the purchasing value of the equipment.

6.5 DATA HANDLING

Since Şişli Etfal Hospital can be included into the category of large-sized hospitals with 118 different types of devices, it will be appropriate to have a computerized documentation system. The benefits of such a system will include easy access to and updating the records of maintenance, testing, calibration, and repairs for each medical device. This approach will be useful for purposes of planning hospital growth, evaluating equipment distribution, replacing equipment and maintaining proper stock of spare parts.

The computer system that will handle documentation can be a Personal Computer which together with the applications will cost around 2.5 millions TL.

6.6 BUDGET

The budget should include the start-up costs, that is the initial capital investment, the manpower, and the operating budget.

The start-up costs will include the costs of the construction for space requirements, office furniture, test equipment and the computer system.

The approximate costs of initial capital investment is given below:

	(in TL.)
Construction and Furniture	1,000,000
Test Equipment	4,000,000
Computer System	2,500,000
TOTAL	7,500,000

The approximate cost of manpower is described early in this chapter (Section 6.2). They total up to 9,360,000 TL.

In addition to the above expenses there will be the expenses of the operating budget including the cost of office supplies, outside service fees, telephone and office expenses, and miscellaneous expenses.

As the numbers imply, the start-up costs of an inhospital biomedical engineering department can be high, but in the long term when the benefits of such a department are considered (refer to Section 2.5), this will be a very profitable investment to make.

VII.

CONCLUSION

In this study, "model" biomedical equipment maintenance programs for hospitals in Turkey are proposed. Prior to the "model", present conditions and current programs in selected hospitals in Turkey were studied which allowed the proposed models to be realistic and applicable. Irrespective of which model applies to individual hospitals, centralized coordination, adequate purchase and acceptance, centralized documentation, effective servicing, in-service training, and intelligent equipment replacement should be provided.

The proposed models are related to the size of the hospitals. In small hospitals, the approach is to hire a medical equipment technician who will interact with shared service organizations and original equipment manufacturer's representatives to ensure proper servicing of biomedical equipment. In a medium sized hospital, a small in-hospital biomedical engineering group can be established to provide adequate servicing of biomedical equipment together with original equipment manufacturer's representatives or shared services. For large hospitals a centralized, in-hospital biomedical engineering department is the best alternative. As indicated in the case study, the structure of the in-hospital biomedical engineering department is dictated by the size of the hospital, and by the amount and types of instrument-

ation. However,for complex and one-of-a-kind devices original equipment manufacturer's representatives' service should be assured.

If properly and effectively provided and managed, these biomedical equipment maintenance programs will lead to improved patient care, minimal risk to patient and hospital personnel due to equipment malfunctions, and effective cost-control.

There are a number of factors that will effect the implementation of these model programs. They are mostly administrative in nature. Even if the hospital administrator understands the need, usefulness and advantages of biomedical equipment maintenance programs,he may not initiate programs and services that are not specifically required by law.

Some of the factors related to this attitude are that there are many people who still view medicine more as an art rather than as a science, and are resistent to the approach that modern medicine must interact with technology and work with engineers and BMETs. Unfortunately, there are fewer engineers and technicians in this discipline than are presently needed. To overcome this problem, more universities should establish appropriate biomedical engineering programs. In order to keep the graduates of these programs in the public health service, they should be paid higher salaries than the industry level.

In addition, standards and regulations should be developed to guide administrators to develop biomedical equipment maintenance programs and improve the delivery of effective health care.

The establishment of effective hospital biomedical equipment maintenance programs in Turkey will contribute significantly to improved cost effective health care.

APPENDICES

APPENDIX A

QUESTIONAIRES

The names of the hospitals participated in the study are:

- SSYB Taksim Hospital
- Istanbul University Haseki Cardiology Institute
- SSK Göztepe Hospital
- Vakıf Guraba Hospital
- Amiral Bristol Hospital

The following biomedical equipment manufacturer's representatives have participated in the survey:

- İncekaralar
- Mesi-Medikal
- Tekser
- Hataş
- Yılmaz Özyürek

The two questionaires used in the survey are presented on the following pages. Starting with page 60, examples from the answers given to the questions by the hospital personnel are provided. On page 62, examples from the biomedical equipment manufacturer's representatives answers are given.

A- HASTANEYİ TANITICI BİLGİLER
1- Adı

2- Niteliği

3- Yatak kapasitesi

4- Görüşülen kişi, ünvanı

B- TEKNİK ELEMANLARI TANITICI BİLGİLER
1- Adet ve ünvan

2- Eğitimleri

3- Uzmanı oldukları cihazlar

4- Tam olarak yetki ve sorumlulukları

5- Ücretleri

6- Çalışma saatleri

7- Kime karşı sorumlular

8- Çalışmaları için ayrılmış yer

C- TIBBİ CİHAZ ALIMI VE KABULÜ

1- Cihaz alınmadan önce bunun gerekliliği, sağlıyacağı faydalar, bulunan cihaza göre avantajları, vs. konularında çalışma yapılıyor mu? (Evet)(Hayır)
Kim tarafından?

2- Şartnameler nasıl ve kimler tarafından hazırlanıyor?

3- Teklifleri değerlendiren seçici kurul kimlerden oluşuyor?

4- Nihayi kararı kim veriyor?

5- Alınmasına karar varilen cihaz hastaneye getirildiğinde belli bir süre ile denenip aranan şartların bulunup bulunmadığı, verimli, arızasız bir şekilde çalışıp çalışmadığı vs. kontrol ediliyor mu? (Evet)(Hayır)

6- Ön kabul ve nihayi kabul deneyleri nasıl ve kimler tarafından yapılıyor?

7- Cihazla birlikte verilen kullanma, bakım, onarım, ve devre şemalarını içeren kitaplar düzenli bir şekilde birarada bulunduruluyor mu? (Evet)(Hayır)
Nerede?

D- TIBBİ CİHAZLARIN BAKIM, ONARIM VE KALİBRASYONU

1- Cihazlar için peryodik bakım ve kalibrasyon programları uygulanıyor mu? (Evet)(Hayır)
Kim tarafından?

2- Bakım, onarım, kalibrasyon ve güvenlik programlarının uygulanması için gerekli test aletleri var mı? (Evet)
(Hayır)

3- Cihazlara uygulanan programların raporları hazırlanıyor ve düzenli bir şekilde dosyalanıyor mu? (Evet)(Hayır)
Bu raporlar kim tarafından değerlendiriliyor?

4- Cihazlar arızaya girdiğinde ya da kazalara sebep olacak şekilde tehlike yarattığında hasta ve sağlık personelini uyarmak üzere etiketler kullanılıyor mu? (Evet)(Hayır)

5- Arızalanan cihazın onarımı, yedek parça ve sarf malzemesi gibi ihtiyaçlar için hastahane dışından servis istendiğinde, firmalar talepleri zamanında ve sorun yaratmadan karşılıyorlar mı? (Evet)(Hayır)
6- Talep edilen ücretler nedir?

E- KAZA ÖNLEME VE KORUNMA PROGRAMLARI

1- Tıbbi cihazlarda meydana gelebilecek arızaların sonucu olarak ortaya çıkabilecek kazalar ve bu kazaların önlenmesi için uyulması gereken kurallar hastahane personeline duyuruluyor mu? (Evet)(Hayır)
Kim tarafından ve ne şekilde?

2- Herhangi bir kaza anında bu kazanın sonuçlarının kontrol altına alınması için koordinatör görevi yapmakla yükümlü bir kimse var mı? (Evet)(Hayır)
3- Kaza kontrolü için yapılan çalışmaların raporları tutuluyor ve değerlendiriliyor mu? (Evet)(Hayır)
Kim tarafından?

F- HASTAHANE PERSONELİNİN EĞİTİMİ

1- Sorumluluklarında bulunan cihazları doğru ve verimli kullanmaları için hastahane personeli eğitiliyor mu? (Evet)
(Hayır)
Kim tarafından?

2- Kazalardan korunma yöntemleri ile ilgili eğitim imkanları var mı? (Evet)(Hayır)

G- Görüşülen kişinin yukarıda belirtilen konularda ortaya çıkan problemlerin çözümü için önerileri:

FİRMANIN ADI

GÖRÜŞÜLEN KİŞİ, ADI VE GÖREVİ

A- DÖKÜMANTASYON

1- Hastanelere, satılan cihazla birlikte aşağıda belirtilen dökümanlar veriliyor mu?

a- Teknik özellikleri içeren kitap (Evet)(Hayır)
b- Kullanım kitabı (Evet)(Hayır)
c- Bakım, onarım, kalibrasyon, mekanik ve elektronik devre şemalarını içeren kitaplar (Evet)(Hayır)
d- Garanti süresini, şartlarını, vs. içeren garanti belgesi (Evet)(Hayır)
e- Kalite kontrol raporu (Evet)(Hayır)
f- Kullanımı için özel altyapı, mekan ve çevre koşulları gerektiren cihazlarda bu talepleri tanımlayan kitap (Evet)(Hayır)

B- SERVİS

1- Garanti süresi bitiminde hastane ile servis sözleşmeleri yapılıyor mu? Çeşitleri ve süreleri?

2- Servis sözleşmelerinde bakım ve onarım için ne tip hizmetler belirtiliyor?

a- Acil servis her zaman yapıabiliyor mu?(Evet)(Hayır)
b- En geç onarıma başlama zamanı tesbit ve garanti ediliyor mu? (Evet)(Hayır)
c- Onarım bitinceye kadar kullanılmak üzere ödünç cihaz verme sistemi var mı? (Evet)(Hayır)

3- Sözleşme yapılmamış ise istek üzerine yapılan servis için talep edilen ücret nedir?
a- Bakım ve kalibrasyon ücretleri

b- Normal mesai saatinde onarım ücreti

c- Mesai saati dışında onarım ucreti

d- Yol ücreti

4- Firma hizmet ve servis sırasında mesleki hatalardan dolayı hasta ve hastane personelinin zarar görebileceği kazalara sebep olma, eşya ve aletleri kırıp bozma gibi durumlarda, hasta ve hastaneye tazminat ödeme yükümlülüğü altına giriyor mu? (Evet)(Hayır)

C- DİĞER HİZMETLER
1- Eğitim
a- Cihazın verimli ve doğru kullanılabilmesi için sorumlu hastane personelini eğitici çalışmalar yapılıyor mu? (Evet)(Hayır)
Nerede ve nasıl?

b- Cihazın çalışma prensibi, bakımı, onarımı ve kalibrasyonu konularını içeren teknik eğitim çalışmaları düzenleniyor mu? (Evet)(Hayır)
Kimlere ve nerede?

2- Alıcıya cihazlardaki son gelişmeler, yeni modeller, modifikasyonlar, ve kazalar ve önlemleri konularında peryodik olarak bilgi sağlanıyor mu? (Evet)(Hayır)
Ne şekilde?

D- Görüşülen kişinin yukarıda belirtilen konularda ortaya çıkan problemlerin çözümü için önerileri nelerdir?

3- Yatak kapasitesi

1218

4- Görüşülen kişi, ünvanı

-

B- TEKNİK ELEMANLARI TANITICI BİLGİLER

1- Adet ve ünvan

1 Elektrik, 1 Makina Mühendisi
1 Makine, 1 Elektronik Yüksek Teknikeri
55 Teknisyen

2- Eğitimleri

2 Üniversite Mezunu, 2 Sanat-Okulu Mezunu
Diğerleri ilk ve orta okul mezunları

3- Uzmanı oldukları cihazlar

2 Eleman EKG, Kuvöz, Elektrofotometre
cihazlarında bilgi sahibi.

7- Cihazla birlikte verilen kullanma, bakım, onarım, ve devre şemalarını içeren kitaplar düzenli bir şekilde birarada bulunduruluyor mu? (Evet)(Hayır ✓)
Nerede?

D- TIBBİ CİHAZLARIN BAKIM, ONARIM VE KALİBRASYONU

1- Cihazlar için peryodik bakım ve kalibrasyon programları uygulanıyor mu? (Evet)(Hayır ✓)
Kim tarafından?
Hastanede bulunan 400 cihazdan sadece bir tanesi için, yapımcı firmanın verdiği program, kullanıcı kişi tarafından uygulanıyor.

2- Bakım, onarım, kalibrasyon ve güvenlik programlarının uygulanması için gerekli test aletleri var mı? (Evet ✓)
(Hayır) Yetersiz

3- Yatak kapasitesi

360

4- Görüşülen kişi, ünvanı

—

B- TEKNİK ELEMANLARI TANITICI BİLGİLER

1- Adet ve ünvan

1 Makina Mühendisi, 15 Vasıfsız Teknisyen

2- Eğitimleri

1 Üniversite mezunu, diğer elemanlar ilkokul ve çeşitli kurs mezunları

3- Uzmanı oldukları cihazlar

Yok

D- TIBBİ CİHAZLARIN BAKIM, ONARIM VE KALİBRASYONU

1- Cihazlar için peryodik bakım ve kalibrasyon programları uygulanıyor mu? (Evet)(Hayır ✓)
Kim tarafından?

2- Bakım, onarım, kalibrasyon ve güvenlik programlarının uygulanması için gerekli test aletleri var mı? (Evet ✓)
(Hayır) Yetersiz

3- Cihazlara uygulanan programların raporları hazırlanıyor ve düzenli bir şekilde dosyalanıyor mu? (Evet)(Hayır ✓)
Bu raporlar kim tarafından değerlendiriliyor?

4- Cihazlar arızaya girdiğinde ya da kazalara sebep olacak şekilde tehlike yarattığında hasta ve sağlık personelini uyarmak üzere etiketler kullanılıyor mu? (Evet)(Hayır ✓)

1- Sorumluluklarında bulunan cihazları doğru ve verimli kullanmaları için hastahane personeli eğitiliyor mu? (Evet ✓)
(Hayır)
Kim tarafından?

Satıcı Firmalar Tarafından

2- Kazalardan korunma yöntemleri ile ilgili eğitim imkanları var mı? (Evet)(Hayır ✓)

B- SERVİS

1- Garanti süresi bitiminde hastane ile servis sözleşmeleri yapılıyor mu? Çeşitleri ve süreleri?

Alıcının isteği doğrultusunda birer yıllık servis sözleşmeleri imzalanıyor.

2- Servis sözleşmelerinde bakım ve onarım için ne tip hizmetler belirtiliyor?

a- Acil servis her zaman yapılabiliyor mu?(Evet ✓*)(Hayır)

b- En geç onarıma başlama zamanı tesbit ve garanti ediliyor mu? (Evet ✓)(Hayır)

c- Onarım bitinceye kadar kullanılmak üzere ödünç cihaz verme sistemi var mı? (Evet ✓+)(Hayır)

*Mevcut Eleman Sayısına, arıza merkezine olan uzaklığa bağlı.
+Stokda cihaz mevcut ise

3- Sözleşme yapılmamış ise istek üzerine yapılan servis için talep edilen ücret nedir?

a- Bakım ve kalibrasyon ücretleri

Cihaza Göre Değişiyor, sabit bir ücret yok.

b- Normal mesai saatinde onarım ücreti

Sabit bir ücret yok

c- Mesai saati dışında onarım ucreti

Sabit bir ücret yok

d- Yol ücreti

Şirket tarafından karşılanıyor

C- DİĞER HİZMETLER

1- Eğitim

a- Cihazın verimli ve doğru kullanılabilmesi için sorumlu hastane personelini eğitici çalışmalar yapılıyor mu? (Evet ✓)(Hayır)

Nerede ve nasıl?

Cihaza bağlı olarak Türkiye'de ya da yurtdışında teknik uzmanlarca düzenlenen kurslar ile.

b- Cihazın çalışma prensibi, bakımı, onarımı ve kalibrasyonu konularını içeren teknik eğitim çalışmaları düzenleniyor mu? (Evet ✓)(Hayır)

Kimlere ve nerede?

Hastanede, mevcut teknik personele.

APPENDIX B

EXAMPLES OF DOCUMENTATION FORMS

The biomedical equipment inventory card on page 64 and acceptance report on page 65 are developed by the Biomedical Engineering Institute at Boğaziçi University.

The inspection form on page 67 is developed by the Emergency Care Research Institute, Pennsylvania. The form is designed for both major and minor inspection of a wide range of devices. For each device, separate items pertain to each inspection. Following the inspection form, two examples are given related to the use of the forms on pages 68 and 69 For more information see number 20 of the Bibliography.

BİOMEDİKAL CİHAZLARI ENVANTER KARTI

ENVANTER NO	CİHAZIN ADI	CİHAZIN SAHİBİ	KULLANILDIĞI YER	KULLANANLARIN ADI ve TELEFONU
BMAE_NO				

DEMİRBAŞ NO	DEMİRBAŞ DEĞERİ	MODELİ ve TİPİ	SERİ NO	SİPARİŞ TARİHİ	
				TESLİM ALINIŞ TARİHİ	

İMALATÇISI ve ADRESİ	SATICISI ADRESİ ve TELEFONU	KATİ KABUL TARİHİ	
		İLK KULLANIŞ TARİHİ	
		İLK KULLANAN	

BAKIM KİTABININ YERİ ve ADEDİ	KULLANMA REHBERİ YERİ ve ADEDİ	AYAR SORUMLUSU	
		BAKIM SORUMLUSU	

DEĞİŞİKLİKLER ve ÖZEL NOTLAR	

ÖN KABUL (MUAYENE) RAPORU

TARİH:_____ CİHAZIN ADI:_____

MUAYENEYİ YAPANLAR:_____ MODELİ TİPİ:_____

SATICISI:_____ SERİ NO:_____

A_MUAYENE SONUÇLARI:

1_Cihaz sağlam gelmiş mi?_____

2_Ambalaj listesi ve faturada bildirilen bütün parçalar ve yedekler gelmiş mi?_____

3_Kullanma rehberi var mı?_____

4_Kullanma rehberinin adedi_____

5_Ayar ve bakım rehberi var mı?_____

6_Ayar ve bakım rehberi adedi_____

7_Bağlantı ve özelkabloları var mı?_____

8_Fişler normal mi yoksa özel mi?_____

9_Alete elektirik giris sigortası var mı?_____

10_Toprak ucunun sasiye olan direnci 0,10 ohm veya daha az mı?_____

11_Şasiden toprağa olan kaçak akım değerleri_____

_Acil bakım cihazlarında 100 mikroamper veya daha az(rms)

_Diger cihazlarda 500 mikroamper veya daha az(rms)

	Normal	Toprak açık	Polaritedeğişince	Toprak açık ve polarite değişik
a_Kapalı iken				
b_Açık iken				

12_Hastaya bağlantı uçlarından toprağa olan kaçak akım:

_Yalıtılmış uçlardan 10 μA veya daha az(Kablo ile 20μA veya daha az)

_Yalıtılmamış uçlardan 50 μA veya daha az

	Normal	Toprak açık	Polarite değişince	Toprak açık ve polarite değişik
a_Kapalı iken				
b_Açık iken				

Yalıtılmış hastaya bağlantı uçlarına 220 volt 50Hz sinyal verilince: (10μA veya daha az kablo ile 20μA veya daha az)

	Normal	Polarite değişince
a_Kapalı iken		
b_Açık iken		

13_Cihazın çalışması için ilave cihaz vs'ye ihtiyaç varsa bildiriniz_____

_____

14_Muayene sonunda

a_Cihaz tamamdır ve çalışabilir☐ _____

b_Cihaz şartnameye uymuyor ☐ _____

c_Cihaz noksandır☐ _____

d_Cihaz arızalıdır☐ _____

e_Gerekli işlem_____

_____

15 Muayene edenlerin imzaları:_____

CONTROL NO._____ LOCATION_____

DEVICE TYPE_____

MANUFACTURER_____

MODEL NO._____ SERIAL NO._____

INSPECTOR_____ DATE_____ CHECKLIST NO._____

INSPECTION ☐ MINOR ☐ MAJOR ☐ ACCEPTANCE

Inspection Form

5200 BUTLER PIKE
PLYMOUTH MEETING
PENNSYLVANIA 19462

System Components	
Control #	Description

Status	
Passed	☐
Service Required	☐
Removed From Service	☐
ESR #	

1	Pass	Fail	QUALITATIVE TESTS	COMMENTS
1.1			CHASSIS/HOUSING	
1.2			MOUNT/FASTENERS	
1.3			CASTERS/BRAKES	
1.4			AC PLUG/ACCESS. OUTLETS	
1.5			LINE CORD	
1.6			STRAIN RELIEFS	
1.7			CIRCUIT BREAKER/FUSE	
1.8			TUBES/HOSES	
1.9			CABLES	
1.10			FITTINGS/CONNECTORS	
1.11			ELECTRODES/XDUCERS	
1.12			FILTERS	
1.13			CONTROLS/SWITCHES	
1.14			HEATER	
1.15			MOTOR/PUMP/FAN/COMP.	
1.16			FLUID LEVELS	
1.17			BATTERY/CHARGER	
1.18			INDICATORS/DISPLAYS	
1.19			USER CALIBRATION	
1.20			ALARMS/INTERLOCKS	
1.21			AUDIBLE SIGNALS	
1.22			LABELING	
1.23			ACCESSORIES	
1.24				
1.25				

2	Pass	Fail	QUANTITATIVE TESTS			COMMENTS
2.1			GROUNDING RES.: _____ Ω			
2.2			MAX. LEAKAGE CURRENT:			
			Chassis: ____ μA Leads: ____ μA			
			Mode: On/Off Norm/Rev.			
2.3						
2.4						
2.5						
2.6						
2.7						
2.8						
2.9						
2.10						
	Units		Set	Indicated	Actual	
2.11						
	Units					
2.12						
	Units					

COMMENTS: _____

3	CHECK IF DONE	P.M.	DESCRIPTION & COMMENTS
3.1		CLEAN	
3.2		LUBRICATE	
3.3		CALIBRATE	
3.4		REPLACE	

CONTROL NO. 7914 LOCATION Surgery
DEVICE TYPE Infusion Pump
MANUFACTURER Company 77
MODEL NO. 291-B SERIAL NO. 291859
INSPECTOR A.R DATE 17/4/86 CHECKLIST NO. 174
INSPECTION ☐ MINOR ☑ MAJOR ☐ ACCEPTANCE

Inspection Form

5200 BUTLER PIKE
PLYMOUTH MEETING
PENNSYLVANIA 19462

System Components	
Control #	Description

Status	
Passed	☐
Service Required	☑
Removed From Service	☐
ESR #	

1	Pass	Fail	QUALITATIVE TESTS	COMMENTS
1.1	✓		CHASSIS/HOUSING	
1.2	✓		MOUNT/FASTENERS	
1.3	✓		CASTERS/BRAKES	
1.4	✓		AC PLUG/ACCESS. OUTLETS	
1.5	✓		LINE CORD	
1.6	✓		STRAIN RELIEFS	
1.7	✓		CIRCUIT BREAKER/FUSE	
1.8		✓	TUBES/HOSES	Breaks in tubes
1.9	✓		CABLES	
1.10		✓	FITTINGS/CONNECTORS	Fittings are loose
1.11			ELECTRODES/XDUCERS	
1.12			FILTERS	
1.13	✓		CONTROLS/SWITCHES	
1.14			HEATER	
1.15			MOTOR/PUMP/FAN/COMP.	
1.16			FLUID LEVELS	
1.17	✓		BATTERY/CHARGER	
1.18	✓		INDICATORS/DISPLAYS	
1.19			USER CALIBRATION	
1.20		✓	ALARMS/INTERLOCKS	Alarms Not Workin
1.21		✓	AUDIBLE SIGNALS	Not functioning
1.22	✓		LABELING	
1.23			ACCESSORIES	
1.24				
1.25				

COMMENTS: Alarms in case of air bubbles and empty bottle are not working.

2	Pass	Fail	QUANTITATIVE TESTS			COMMENTS
2.1	✓		GROUNDING RES.: 0.2 Ω			
2.2	✓		MAX. LEAKAGE CURRENT: 70 μA			
			Chassis: ____ μA Leads: ____ μA			
			Mode: On/Off Norm/Rev.			
2.3						
2.4						
2.5						
2.6						
2.7						
2.8						
2.9						
2.10		✓	Rate Accuracy			
	Units		Set	Indicated	Actual	
	ml		low	50	62	
			high	100	79	
2.11						
	Units					
2.12						
	Units					

3	CHECK IF DONE	P.M.	DESCRIPTION & COMMENTS
3.1	✓	CLEAN	
3.2		LUBRICATE	
3.3		CALIBRATE	
3.4		REPLACE	

CONTROL NO. 2342 LOCATION Cardiology
DEVICE TYPE Defibrillators
MANUFACTURER Company X
MODEL NO. S/2A SERIAL NO. 2397-5
INSPECTOR J.K DATE 2/4/85 CHECKLIST NO. 24
INSPECTION ☑ MINOR ☐ MAJOR ☐ ACCEPTANCE

Inspection Form

5200 BUTLER PIKE
PLYMOUTH MEETING
PENNSYLVANIA 19462

System Components	
Control #	Description
2342-1	Paddles

Status	
Passed	✓
Service Required	☐
Removed From Service	☐
ESR #	792

1	Pass	Fail	QUALITATIVE TESTS	COMMENTS
1.1	✓		CHASSIS/HOUSING	
1.2	✓		MOUNT/FASTENERS	
1.3	✓		CASTERS/BRAKES	
1.4		✓	AC PLUG/ACCESS. OUTLETS	Need Fixing
1.5	✓		LINE CORD	
1.6	✓		STRAIN RELIEFS	
1.7	✓		CIRCUIT BREAKER/FUSE	
1.8			TUBES/HOSES	
1.9		✓	CABLES	Some broken
1.10	✓		FITTINGS/CONNECTORS	
1.11	✓		ELECTRODES/XDUCERS	
1.12			FILTERS	
1.13	✓		CONTROLS/SWITCHES	
1.14			HEATER	
1.15			MOTOR/PUMP/FAN/COMP.	
1.16			FLUID LEVELS	
1.17	✓		BATTERY/CHARGER	
1.18	✓		INDICATORS/DISPLAYS	
1.19			USER CALIBRATION	
1.20			ALARMS/INTERLOCKS	
1.21			AUDIBLE SIGNALS	
1.22	✓		LABELING	
1.23	✓		ACCESSORIES	
1.24	✓		INTERNAL DISCHARGE	
1.25				

2	Pass	Fail	QUANTITATIVE TESTS	COMMENTS
2.1	✓		GROUNDING RES.: 0.25Ω	
2.2			MAX. LEAKAGE CURRENT:	
			Chassis: ___ μA Leads: ___ μA	
			Mode: On/Off Norm/Rev.	
2.3				
2.4				
2.5	✓		Charging Time to Max.	10th charge 12 sec.
2.6				
2.7				
2.8				
2.9				
2.10	✓		Output Energy: Low and Max	85% of indicated energy, 300 joules
	Units		Set / Indicated / Actual	
2.11				
	Units			
2.12				
	Units			

COMMENTS: Plugs are fixed, and broken cables are repaired

3	CHECK IF DONE	P.M.	DESCRIPTION & COMMENTS
3.1	✓	CLEAN	
3.2		LUBRICATE	
3.3		CALIBRATE	
3.4		REPLACE	

APPENDIX C

LIST OF BIOMEDICAL EQUIPMENTS IN ŞIŞLI ETFAL HOSPITAL

The following list of devices in each user department in Şişli Etfal Hospital is obtained from the 'Biomedical Devices Inventory Survey' done by the Biomedical Engineering Institute at Boğaziçi University. For more information about the results of the survey, see number 16 of the Bibliography.

ASPIRATOR	1. COCUK
ASPIRATOR CERRAHI	1. COCUK
EKG	1. COCUK
MIKROSKOP	1. COCUK
MIKROSKOP	1. COCUK
NEBULIZER	1. COCUK
SANTRIFUJ	1. COCUK
EKG	1. DAHILIYE
MIKROSKOP BINOKULER	1. DAHILIYE
SANTRIFUJ	1. DAHILIYE
SANTRIFUJ HEMATOKRIT	1. DAHILIYE
TEMEL METABOLIZMA BIRIMI	1. DAHILIYE
AMELIYAT LAMBASI	1. DOGUM
AMELIYAT LAMBASI	1. DOGUM
AMELIYAT LAMBASI AKULU	1. DOGUM
AMELIYAT LAMBASI SEYYAR	1. DOGUM
AMELIYAT MASASI	1. DOGUM
AMELIYAT MASASI	1. DOGUM
ASPIRATOR	1. DOGUM
ASPIRATOR	1. DOGUM
ASPIRATOR	1. DOGUM
ASPIRATOR	1. DOGUM
ASPIRATOR	1. DOGUM
ASPIRATOR	1. DOGUM
ASPIRATOR	1. DOGUM
DOGUM MASASI	1. DOGUM
DOGUM MASASI	1. DOGUM
DOGUM MASASI	1. DOGUM
DOGUM MASASI	1. DOGUM
DOGUM MASASI	1. DOGUM
DOGUM MASASI	1. DOGUM
DOGUM MASASI	1. DOGUM
DOGUM MASASI	1. DOGUM
ELEKTROKOTER	1. DOGUM
ETUV & OTOKLAV	1. DOGUM
ETUV BUHARLI	1. DOGUM
ETUV BUHARLI	1. DOGUM
ETUV BUHARLI	1. DOGUM
ETUV BUHARLI	1. DOGUM
ETUV KURU	1. DOGUM
ETUV KURU	1. DOGUM
FETAL MONITOR	1. DOGUM
INSUFLASYON CIHAZI	1. DOGUM
ISIK KAYNASI	1. DOGUM
ISIK KAYNASI	1. DOGUM
JINEKOLOJIK MUAYENE MASASI	1. DOGUM
JINEKOLOJIK MUAYENE MASASI	1. DOGUM
JINEKOLOJIK MUAYENE MASASI	1. DOGUM
KOAGULATOR	1. DOGUM
KOLPOSKOP	1. DOGUM
MIKROSKOP	1. DOGUM
SANTRIFUJ	1. DOGUM
TARAYICI DOPPLER	1. DOGUM
TARAYICI DOPPLER	1. DOGUM
TARAYICI ULTRASON	1. DOGUM

ASPIRATOR	1. HARICIYE
ASPIRATOR	1. HARICIYE
ASPIRATOR	1. HARICIYE
ETUV KURU	2. COCUK
MIKROSKOP	2. COCUK
MIKROSKOP	2. COCUK
ASPIRATOR	2. DAHILIYE
ASPIRATOR	2. DAHILIYE
ASPIRATOR	2. DAHILIYE
DEFIBRILATOR MONITOR	2. DAHILIYE
EKG	2. DAHILIYE
EKG	2. DAHILIYE
EKG MONITOR	2. DAHILIYE
MIKROSKOP	2. DAHILIYE
MIKROSKOP	2. DAHILIYE
SANTRIFUJ	2. DAHILIYE
SANTRIFUJ	2. DAHILIYE
SANTRIFUJ HEMATOKRIT	2. DAHILIYE
AMELIYAT LAMBASI	2. DOGUM
AMELIYAT LAMBASI	2. DOGUM
AMELIYAT LAMBASI SEYYAR	2. DOGUM
AMELIYAT MASASI	2. DOGUM
AMELIYAT MASASI	2. DOGUM
ANESTEZI CIHAZI	2. DOGUM
ARITMA BIRIMI	2. DOGUM
ASPIRATOR	2. DOGUM
ASPIRATOR	2. DOGUM
ASPIRATOR	2. DOGUM
ASPIRATOR	2. DOGUM
DOGUM MASASI	2. DOGUM
DOGUM MASASI	2. DOGUM
DOGUM MASASI	2. DOGUM
DOGUM MASASI	2. DOGUM
ELEKTROKOTER	2. DOGUM
ELEKTROKOTER	2. DOGUM
ETUV	2. DOGUM
ETUV	2. DOGUM
ETUV	2. DOGUM
ETUV	2. DOGUM
ETUV KAYNATMALI	2. DOGUM
ETUV KAYNATMALI	2. DOGUM
INSUFLASYON CIHAZI	2. DOGUM
JINEKOLOJIK MUAYENE MASASI	2. DOGUM
JINEKOLOJIK MUAYENE MASASI	2. DOGUM
JINEKOLOJIK MUAYENE MASASI	2. DOGUM
JINEKOLOJIK MUAYENE MASASI	2. DOGUM
JINEKOLOJIK MUAYENE MASASI	2. DOGUM
JINEKOLOJIK MUAYENE MASASI	2. DOGUM
JINEKOLOJIK MUAYENE MASASI	2. DOGUM
KOLPOSKOP	2. DOGUM
MIKROSKOP	2. DOGUM
OTOKLAV	2. DOGUM
OTOKLAV	2. DOGUM
OTOKLAV	2. DOGUM
SANTRIFUJ	2. DOGUM

TARAYICI DOPPLER	2. DOGUM
TARAYICI DOPPLER	2. DOGUM
ASPIRATOR	2. HARICIYE
ASPIRATOR	2. HARICIYE
ASPIRATOR	2. HARICIYE
ETUV	2. HARICIYE
ASPIRATOR	3. COCUK
ASPIRATOR	3. COCUK
MIKROSKOP	3. COCUK
MIKROSKOP	3. COCUK
EKG	3. DAHILIYE
ETUV	3. DAHILIYE
ETUV KURU	3. DAHILIYE
MIKROSKOP	3. DAHILIYE
MIKROSKOP BINOKULER	3. DAHILIYE
SANTRIFUJ	3. DAHILIYE
SANTRIFUJ	3. DAHILIYE
SANTRIFUJ HEMATOKRIT	3. DAHILIYE
ASPIRATOR	3. HARICIYE
ASPIRATOR	3. HARICIYE
ASPIRATOR	3. HARICIYE
GASTROSKOP	3. HARICIYE
EKG	4. DAHILIYE
MIKROSKOP	4. DAHILIYE
SANTRIFUJ	4. DAHILIYE
SANTRIFUJ HEMATOKRIT	4. DAHILIYE
AMELIYAT MASASI	ACIL CERRAHI
ANESTEZI CIHAZI	ACIL CERRAHI
EKG	ACIL DAHILIYE
AMELIYAT LAMBASI	ACIL SERVIS
AMELIYAT LAMBASI	ACIL SERVIS
AMELIYAT MASASI	AMELIYATHANE
AMELIYAT MASASI	AMELIYATHANE
ANESTEZI CIHAZI	AMELIYATHANE
ANESTEZI CIHAZI	ANESTEZI
ARITMA BIRIMI	BAKTERIOLOJI
ETUV	BAKTERIOLOJI
ETUV	BAKTERIOLOJI
ETUV	BAKTERIOLOJI
ETUV	BAKTERIOLOJI
ETUV	BAKTERIOLOJI
MIKROSKOP	BAKTERIOLOJI
MIKROSKOP	BAKTERIOLOJI
MIKROSKOP	BAKTERIOLOJI
MIKROSKOP	BAKTERIOLOJI
MIKROSKOP	BAKTERIOLOJI
MIKROSKOP	BAKTERIOLOJI
MIKROSKOP	BAKTERIOLOJI
MIKSER	BAKTERIOLOJI

ETUVLI?	BAKTERIOLOJI
SANTRIFUJ	BAKTERIOLOJI
SANTRIFUJ	BAKTERIOLOJI
SANTRIFUJ	BAKTERIOLOJI
SANTRIFUJ	BAKTERIOLOJI
SPEKTROFOTOMETRE	BAKTERIOLOJI
SU BANYOSU BAIN MARIE	BAKTERIOLOJI
TERAZI MEKANIK	BAKTERIOLOJI
AMELIYAT LAMBASI	BEYIN CERRAHI
AMELIYAT MASASI	BEYIN CERRAHI
ANESTEZI CIHAZI	BEYIN CERRAHI
APNEA MONITOR	BEYIN CERRAHI
ASPIRATOR	BEYIN CERRAHI
ASPIRATOR	BEYIN CERRAHI
ASPIRATOR	BEYIN CERRAHI
ASPIRATOR	BEYIN CERRAHI
ASPIRATOR	BEYIN CERRAHI
BASINC MONITOR	BEYIN CERRAHI
BASINC MONITOR	BEYIN CERRAHI
DEFIBRILATOR DC	BEYIN CERRAHI
DEFIBRILATOR MONITOR	BEYIN CERRAHI
DEFIBRILATOR PROGRAMCISI	BEYIN CERRAHI
EKG MONITOR	BEYIN CERRAHI
ELEKTROKOTER	BEYIN CERRAHI
ELEKTROKOTER	BEYIN CERRAHI
ETUV	BEYIN CERRAHI
FIZYOLOJIK MONITOR	BEYIN CERRAHI
FIZYOLOJIK MONITOR	BEYIN CERRAHI
FIZYOLOJIK MONITOR	BEYIN CERRAHI
KOAGULATOR	BEYIN CERRAHI
KOMPRESOR HAVA	BEYIN CERRAHI
MATKAP	BEYIN CERRAHI
MATKAP	BEYIN CERRAHI
RESPIRATOR	BEYIN CERRAHI
SANTRAL MONITOR	BEYIN CERRAHI
SICAKLIK MONITOR	BEYIN CERRAHI
SICAKLIK MONITOR	BEYIN CERRAHI
SOLUNUM MONITOR	BEYIN CERRAHI
YATAKBASI MONITOR	BEYIN CERRAHI
YATAKBASI MONITOR	BEYIN CERRAHI
YATAKBASI MONITOR	BEYIN CERRAHI
YATAKBASI MONITOR	BEYIN CERRAHI
YATAKBASI MONITOR	BEYIN CERRAHI
ARITMA BIRIMI	BIOKIMYA
ARITMA BIRIMI	BIOKIMYA
ELEKTROFOREZ	BIOKIMYA
ETUV	BIOKIMYA
ETUV	BIOKIMYA
FLAME FOTOMETRE	BIOKIMYA
FLAME FOTOMETRE	BIOKIMYA

		AMELIYAT MASASI	DEPO
BAZOMETRE DRETED ALKALI	BIOKIMYA	ASPIRATÖR CERRAHI	ENFEKSIYON HASTALIKLARI
HASSAS TERAZI	BIOKIMYA	ETUV	ENFEKSIYON HASTALIKLARI
HASSAS TERAZI	BIOKIMYA	ETUV	ENFEKSIYON HASTALIKLARI
HASSAS TERAZI	BIOKIMYA	MIKROSKOP	ENFEKSIYON HASTALIKLARI
HASSAS TERAZI	BIOKIMYA	MIKROSKOP BINOKÜLER	ENFEKSIYON HASTALIKLARI
KOAGÜLOMETRE	BIOKIMYA	SANTRIFUJ	ENFEKSIYON HASTALIKLARI
KROMATOGRAFI INCE TABAKA	BIOKIMYA	DIATERMI BIRIMI KISADALGA	FIZIK TEDAVI
MIKROSKOP	BIOKIMYA	DIATERMI BIRIMI KISADALGA	FIZIK TEDAVI
MIKROSKOP	BIOKIMYA	DIATERMI BIRIMI MIKRODALGA	FIZIK TEDAVI
PH METRE	BIOKIMYA	DIATERMI BIRIMI ULTRASONIK	FIZIK TEDAVI
PH METRE	BIOKIMYA	DIATERMI BIRIMI ULTRASONIK	FIZIK TEDAVI
SANTRIFUJ	BIOKIMYA	ENFRARUJ CIHAZI	FIZIK TEDAVI
SANTRIFUJ	BIOKIMYA	ENFRARUJ LAMBASI	FIZIK TEDAVI
SANTRIFUJ	BIOKIMYA	ENFRARUJ ULTRAVIOLE CIHAZI	FIZIK TEDAVI
SANTRIFUJ	BIOKIMYA	GALVANI FARADI CIHAZI	FIZIK TEDAVI
SANTRIFUJ	BIOKIMYA	GALVANI FARADI CIHAZI	FIZIK TEDAVI
SPEKTROFOTOMETRE	BIOKIMYA	GALVANI FARADI CIHAZI	FIZIK TEDAVI
SPEKTROFOTOMETRE	BIOKIMYA	GALVANI FARADI CIHAZI	FIZIK TEDAVI
SPEKTROFOTOMETRE	BIOKIMYA	GALVANI FARADI CIHAZI	FIZIK TEDAVI
SPEKTROFOTOMETRE	BIOKIMYA	HYDROCOLLATOR	FIZIK TEDAVI
SPEKTROMETRE	BIOKIMYA	OMUZ ISITMA CIHAZI	FIZIK TEDAVI
SPEKTROMETRE	BIOKIMYA	PARAFIN BANYOSU	FIZIK TEDAVI
SU BANYOSU BAIN MARIE	BIOKIMYA	SICAK HAVA CIHAZI	FIZIK TEDAVI
SU BANYOSU BAIN MARIE	BIOKIMYA	SICAK HAVA CIHAZI (SOCAK)	FIZIK TEDAVI
ÇOÇ DONDURUCU	BUYUK ENFEKSIYON	TRAKSIYON CIHAZI	FIZIK TEDAVI
ETUV	BUYUK ENFEKSIYON	TRAKSIYON CIHAZI	FIZIK TEDAVI
MIKROSKOP	BUYUK ENFEKSIYON	TRAKSIYON CIHAZI	FIZIK TEDAVI
MIKROSKOP	BUYUK ENFEKSIYON	TRAKSIYON CIHAZI	FIZIK TEDAVI
MIKROTOM	BUYUK ENFEKSIYON	TRAKSIYON MASASI	FIZIK TEDAVI
OTOTERMIKON	BUYUK ENFEKSIYON	TRAKSIYON MASASI	FIZIK TEDAVI
SANTRIFUJ	BUYUK ENFEKSIYON	AMELIYAT LAMBASI	GOZ
AMELIYAT MASASI	CERRAHI	AMELIYAT LAMBASI	GOZ
ANESTEZI CIHAZI	CERRAHI	AMELIYAT MASASI	GOZ
RESPIRATOR	CERRAHI	AMELIYAT MASASI	GOZ
ELEKTROKOTER	CILDIYE	ANESTEZI CIHAZI	GOZ
ELEKTROKOTER	CILDIYE	ELEKTROKOTER	GOZ
ENFRARUJ ULTRAVIOLE CIHAZI	CILDIYE	ETUV	GOZ
MIKROSKOP MANUPILATORU	CILDIYE	KIROSIRURJI BIRIMI	GOZ
ETUV	COCUK ENFEKSIYON	KIROSIRURJI BIRIMI	GOZ
ETUV	COCUK ENFEKSIYON	KRIYOJEN	GOZ
MIKROSKOP	COCUK ENFEKSIYON	MATKAP	GOZ
MIKROSKOP	COCUK ENFEKSIYON	MIKROSKOP AMELIYAT OFTALMOJIK	GOZ
SANTRIFUJ	COCUK ENFEKSIYON	AMELIYAT MASASI	KARDIYE
DONDURUCU KAN	DAHILIYE	ANESTEZI CIHAZI	KARDIYE
ETUV	DAHILIYE	AMELIYAT LAMBASI SABIT	KARDIYE CERRAHI
ETUV	DAHILIYE	AMELIYAT LAMBASI SEYYAR	KAN MERKEZI
ETUV	DAHILIYE	ARITMA BIRIMI	KAN MERKEZI
HASSAS TERAZI	DAHILIYE	FILTRE CIHAZI	KAN MERKEZI
MIKROSKOP	DAHILIYE	SOGUTUCU	KAN MERKEZI
PH METRE	DAHILIYE	SOGUTUCU	KAN MERKEZI
PH METRE	DAHILIYE	AMELIYAT LAMBASI SEYYAR	KBB
SANTRIFUJ	DAHILIYE	AMELIYAT MASASI	KBB
SANTRIFUJ	DAHILIYE	ANESTEZI CIHAZI	KBB
SU BANYOSU BAIN MARIE	DAHILIYE	ASPIRATOR	KBB
		ASPIRATOR	KBB

ASPIRATOR	KBB
ELEKTROKOTER	KBB
ETUV	KBB
MIKROSKOP AMELIYAT	KBB
ODYOMETRE	KBB
ODYOMETRE	KBB
DEFIBRILATOR MONITOR	KORONER BAKIM
EKG	KORONER BAKIM
EKG MONITOR	KORONER BAKIM
EKG MONITOR	KORONER BAKIM
EKG MONITOR	KORONER BAKIM
EKG MONITOR	KORONER BAKIM
EKG MONITOR	KORONER BAKIM
EKG MONITOR	KORONER BAKIM
ETUV KAYNATMALI	KORONER BAKIM
KALP PILLERI	KORONER BAKIM
SANTRAL MONITOR	KORONER BAKIM
ASPIRATOR	NOROLOJI
AVERAGER	NOROLOJI
DIATERMI BIRIMI KISADALGA	NOROLOJI
EEG	NOROLOJI
EMG	NOROLOJI
MIKROSKOP	NOROLOJI
NEUROTON FARADI	NOROLOJI
SANTRIFUJ	NOROLOJI
ELEKTROKOTER	NOROSIRURJI
ETUV	NOROSIRURJI
ETUV	NOROSIRURJI
MIKROSKOP	NOROSIRURJI
SANTRIFUJ	NOROSIRURJI
SANTRIFUJ	NOROSIRURJI
SERIOGRAFI	NOROSIRURJI
AMELIYAT LAMBASI	ORTOPEDI
AMELIYAT LAMBASI	ORTOPEDI
AMELIYAT MASASI	ORTOPEDI
ANESTEZI CIHAZI	ORTOPEDI
ETUV	ORTOPEDI
RONTGEN CIHAZI DONER	ORTOPEDI
AMELIYAT LAMBASI SEYYAR	PREMATURE
ASPIRATOR	PREMATURE
ETUV BUHARLI	PREMATURE
KUVOZ BEBEK	PREMATURE
KUVOZ BEBEK	PREMATURE
KUVOZ BEBEK	PREMATURE
KUVOZ BEBEK	PREMATURE
KUVOZ BEBEK TASIMA	PREMATURE
RESUSITATOR BEBEK	PREMATURE
RADYOGRAFIK MASA BUKI	RADYOLOJI
RADYOGRAFIK MASA BUKI	RADYOLOJI
RADYOGRAFIK MASA BUKI	RADYOLOJI
RADYOGRAFIK MASA BUKI	RADYOLOJI
RADYOGRAFIK MASA BUKI	RADYOLOJI
RADYOGRAFIK MASA BUKI + TUB	RADYOLOJI
RADYOGRAFIK MASA VERTIKAL	RADYOLOJI
RADYOGRAFIK MASA YATAR KALKAR	RADYOLOJI
RONTGEN CIHAZI	RADYOLOJI
RONTGEN CIHAZI	RADYOLOJI
RONTGEN CIHAZI KONTROL MASASI	RADYOLOJI
RONTGEN CIHAZI KONTROL MASASI	RADYOLOJI
RONTGEN CIHAZI KONTROL MASASI	RADYOLOJI
RONTGEN CIHAZI KONTROL MASASI	RADYOLOJI
RONTGEN CIHAZI PORTATIF	RADYOLOJI
RONTGEN CIHAZI STAND	RADYOLOJI
RONTGEN CIHAZI TUB	RADYOLOJI
RONTGEN CIHAZI TUB	RADYOLOJI
RONTGEN TUBU VE STAND	RADYOLOJI
RONTGEN TUBU VE STAND	RADYOLOJI
RONTGEN TUBU VE STAND	RADYOLOJI
RONTGEN TUPU SINEMATOGRAFI	RADYOLOJI
SENOGRAF	RADYOLOJI
TOMOGRAFI CIHAZI BUKI MASASI	RADYOLOJI
TOMOGRAFI CIHAZI TUBU	RADYOLOJI
TOMOGRAFI GUC KAYNAGI	RADYOLOJI
TOMOGRAFI KLETI	RADYOLOJI
TUP SOKETI	RADYOLOJI
TV MONITOR	RADYOLOJI
TV MONITOR	RADYOLOJI
TV MONITOR & IMAGING INTENSIFIER	RADYOLOJI
X-ISINI YIKAMA DONANIMI	RADYOLOJI
YATAR KALKAR MASA	RADYOLOJI
BASINC MONITOR	REANIMASYON
BASINC OLCME AYGITI	REANIMASYON
BASINC OLCME AYGITI	REANIMASYON
EKG	REANIMASYON
FIZYOLOJIK MONITOR	REANIMASYON
FIZYOLOJIK MONITOR	REANIMASYON
FIZYOLOJIK MONITOR	REANIMASYON
RESPIRATOR (VANTILATOR)	REANIMASYON
RESPIRATOR (VANTILATOR)	REANIMASYON
RESPIRATOR (VANTILATOR)	REANIMASYON
SICAKLIK MONITOR	REANIMASYON
SICAKLIK MONITOR	REANIMASYON
SICAKLIK MONITOR	REANIMASYON
SICAKLIK MONITOR	REANIMASYON
SOLUNUM MONITOR	REANIMASYON
SOLUNUM MONITOR	REANIMASYON
YATAKBASI MONITOR	REANIMASYON
YATAKBASI MONITOR	REANIMASYON
YATAKBASI MONITOR	REANIMASYON
YATAKBASI MONITOR	REANIMASYON
YATAKBASI MONITOR	REANIMASYON
EEG	REANIMASYON
FIZYOLOJIK MONITOR	REANIMASYON
AMELIYAT LAMBASI	UROLOJI
AMELIYAT LAMBASI SEYYAR	UROLOJI
AMELIYAT MASASI	UROLOJI
AMELIYAT MASASI	UROLOJI
ANESTEZI CIHAZI	UROLOJI
ASPIRATOR	UROLOJI
ASPIRATOR	UROLOJI
ASPIRATOR	UROLOJI
ELEKTROKOTER	UROLOJI
ELEKTROKOTER	UROLOJI
ETUV	UROLOJI
MIKROSKOP	UROLOJI
RONTGEN CIHAZI	UROLOJI
SANTRIFUJ	UROLOJI
URETROSKOP	UROLOJI
DISPLAY OSILOSKOP	YOGUN BAKIM
SANTRAL MONITOR	YOGUN BAKIM

BIBLIOGRAPHY

1. Ben-Zvi, S., Gottlieb,W.,"The Hospital Instrumentation Department:Delivering Clinical Engineering Services to the Hospital Community", Journal of Clinical Engineering, 1:(1) 2-15, 1976.
2. Ben-Zvi, S.,"Development of Preventive Maintenance Procedures", Journal of Clinical Engineering, 9:(2),1984.
3. "Biomedical Engineering Quality Assurance Study:Erlanger Medical Center, Chattanooga, TN.", Project No 415-125, Emergency Care Research Research Institute, November 1983.
4. "Biomedical Technology Risk Assessment Work Sheets", Emergency Care Research Institute.
5. Cheng, M., Prud'homme, J., "Shared Biomedical Engineering: A Cost-Benefit Analysis",
6. "Guideline for Establishing and Administering Medical Instrumentation Maintenance Programs", Association for the Advancement o Medical Instrumentation, 1983.
7. "Guidelines for Clinical Engineering Shared Services", Canadian Medical and Biological Engineering Society, Clinical Engineering Shared-Service Committee, June 1982.

8. "Health Care Technology- Directions for the 1980s",Papers presented at the ECRI Seminar at Boğaziçi University, İstanbul, March 1983.

9. Irnich, W., Miethe, B., "Results of a Clinical Engineering Programme in the Federal Republic of Germany", Medical and Biological Engineering and Computing, March 1984, 98-101.

10. "Management of Equipment", British Department of Health and Social Security,Health Equipment Information, No 98 January 1982.

11. "Medical Equipment Management in Hospitals", American Society For Hospital Engineering, 1978.

12. Ostrander, L.E.,"Presentation of the Clinical Engineering Role to Hospital Administrators", Journal of Clinical Engineering, 4:(1) 11-19, 1979.

13. Patterson, J., Guignon,E., Bronzino,J.D.,"Development of an Inservice Educational Program for Clinical Staff", Journal of Clinical Engineering, 9:(2) 113-120, 1984.

14. Simendinger, E.A., Carver, M.E., Wood, L.M., "Developing a Strategy for Managing the Hospital's Growing Technology", Journal of Clinical Engineering, 8:(2) 109-117.

15. Scott, R.N., Paasche, P.E., "Considerations in the Development of a Regional Clinical Engineering Service", Medical and Biological Engineering and Computing, March 1984.

16. "Tıp Cihazları Envanteri, Şişli Etfal Hastanesi", Biyomedikal Mühendisliği Enstitüsü Projesi, Boğaziçi Üniversitesi, 1985.

17. Tanyolaç, N.," BM 500 Hospital Clinical Engineering and Management" course notes, 1984.

18. "The Equipment Control Program: An Overview", Emergency Care Research Intitute, Health Devices, 8:(10-11) 223-245, 1979.

19. "Tıbbi Cihaz Alımında ve Teknik Şartnamelerin Hazırlanmasında Uyulacak Esaslar", Devlet Planlama Teşkilatı, 1983.

20. "Using the New Checklists and Form", Emergency Care Research Institute, Health Devices, 8:(4) 72-96,1985.