Design of management programme for a clinical engineering department

A Thesis submitted in partial fulfillment of the requirements for the M.Sc. Degree in Biomedical Engineering

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الآية

بسم الله الرحمن الرحيم

(قَالُواْ سُبْحَانَكَ لاَ عِلْمَ لَنَا إِلاَّ مَا عَلَّمْتَنَا إِنَّكَ أَنتَ الْعَلِيمُ الْحَكِيمُ)

(سورة البقرة (32) }

صدق الله العظيم
Dedication

My dear father

I dedicate to you this project

For helping me to become what I am today

For helping me achieve my dreams

For the moral and financial support
ACKNOWLEDGMENT

My grateful thanks to Allah for guiding me and help me to find my way with HIS name and blesses.

My thanks to Dr. Mawia Ahmed Hassan for being a great support for me as a supervisor.

My thanks to my mother, my sister and brothers.
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<td>CE</td>
<td>Clinical Engineer</td>
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<td>CED</td>
<td>Clinical Engineering Department</td>
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<td>CMMS</td>
<td>Computerized maintenance management systems</td>
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<td>CMMIS</td>
<td>Computerized Maintenance Management Information System</td>
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<td>DAO</td>
<td>Data Access Objects</td>
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<td>EOC</td>
<td>Environment Of Care</td>
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<td>FDA</td>
<td>Food And Drag Admiration</td>
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<td>HIS</td>
<td>Hospital Information System</td>
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<td>ICU</td>
<td>Intensive Care Unit</td>
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<td>ID</td>
<td>Identity Document</td>
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<td>MEMP</td>
<td>Medical Equipment Management Program</td>
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<td>MS</td>
<td>Microsoft Access</td>
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<td>OP</td>
<td>Out Patient</td>
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<tr>
<td>OR</td>
<td>Operating Room</td>
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<td>PACS</td>
<td>Picture Archiving And Commutation System</td>
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<td>PM</td>
<td>Preventive Maintenance</td>
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<td>RCA</td>
<td>Root Cause Analysis</td>
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<td>RFID</td>
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<td>SD</td>
<td>Secure Digital</td>
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<td>SMDA</td>
<td>Safe Medical Devices Act</td>
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<td>SQL</td>
<td>Structured Query Language</td>
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<td>VBA</td>
<td>Visual Basic For Applications</td>
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Abstract

Clinical engineering using of biomedical engineering in the health institutions in order to provide excellent health services by adjusting the purchase of equipment and their uses and maintenance standards.

The goal of the project is to design a program that helps in the management and organization the department of clinical engineering in health institutions. The project was accomplished using micro soft access programming language.

The program depends on the inventory of the devices in the health institution. program helps engineer and assistants in the medical engineering department in medical device coding and timing of maintenance time with possibly save manual of medical equipment troubleshooting, the program analyzes data from request that help in the process of buying new medical equipment. Reports are made based on the results of the screening devices, where the piece will help determine the best schedule instead of the comprehensive survey of the devices at a time.

As a result of the program management of clinical engineering department could find organization of work and save time leads to improved performance.
المستخلص

الهندسة الإكلينيكية هي استخدام وسائل الهندسة الطبية في المؤسسات الصحية بهدف تقديم خدمات صحية مميزة من خلال ضبط معايير شراء الأجهزة واستخدامها وصيانةها.

الهدف من المشروع هو تصميم برنامج يساعد في إدارة وتنظيم قسم الهندسة الطبية في المؤسسات الصحية. تم إنجاز المشروع باستخدام لغة برمجة مايكروسوفت إكسس.

يعتمد البرنامج على جرد للاجهزة الموجودة في المؤسسة الصحية. يساعد البرنامج المهندس والمساعدان في قسم الهندسة الطبية في ترميز الأجهزة الطبية وتوقيت وقت الصيانة مع اماكنية حفظ كتيب الأجهزة الطبية وحلولها. يقوم البرنامج بتحليل بيانات الأجهزة المستخدمة واعطالها التي تساعد في عملية شراء الأجهزة الطبية الجديدة. يتم عمل تقارير بناءً على نتائج فحص الأجهزة، حيث يساعد ذلك على تحديد جدولة أفضل بدلاً من المسح الشامل للأجهزة في كل مرة.

كنتيجة للبرنامج ادارة قسم الهندسة الإكلينيكية تنظيم العمل وتوفير الوقت الذي يؤدي على تحسين الاداء.
CHAPTER ONE

Introduction

1.1 General view

In many hospitals, administrators have established clinical engineering departments to manage effectively all the technological resources, especially those relating to medical equipment, that are necessary for providing patient care. The primary objective of these departments is to provide a broad-based engineering program that addresses all aspects of medical instrumentation and systems support the past. Changes in the health care delivery system will dictate that clinical engineering departments justify their performance and existence on the same basis as any business, the performance of specific functions at a high-quality level and at a competitive cost.

Clinical engineering management philosophy must change from a purely task-driven methodology to one that includes the economics of department performance. Indicators need to be developed to measure this performance. Indicator data will need to be collected and analyzed. The data and indicators must be objective and defensible. If it cannot be measured, it cannot be managed effectively [1].

Medical devices are assets that directly affect human lives. They are considerable investments and in many cases have high maintenance costs. It is important, therefore to have a well-planned and managed maintenance program that is able to keep the medical equipment in a health-care institution reliable, safe and available for use when it is needed for diagnostic procedures, therapy, treatments and monitoring of patients. In
addition, such a program prolongs the useful life of the equipment and minimizes the cost of equipment ownership.

The facility maintenance managers should ensure that the equipment are safe to use and complies with all required standards. Equipment should meet the specified performance criteria and should not be damaged. They should also match with the order and arrive complete with specified accessories. Equipment should be placed on a routine maintenance program and the maintenance personnel must be trained and conversant with its use and servicing arrangements [2].

Computerized maintenance management systems (CMMS) are required to manage and control asset, plant, and equipment maintenance in today’s hospitals. A CMMS is much more than just a way to schedule preventive maintenance (PM). By using a CMMS, you can create equipment logs to record events associated with a piece of equipment; create work orders automatically according to a schedule or manually from service requests; record authorized uses of equipment; and track scheduled services or PMs, training, maintenance history, employee time, downtime of a device, parts inventory, purchase orders, and much more [3].

1.2 Problem statement

In many hospitals there is no software system in clinical engineering department there for CE management program will help in work organization and avoid data loses.

1.3 Objectives

1.3.1 General Objectives:
The main general objective of this project is a design of clinical engineering department management program.

1.3.2 Specific Objectives:
1. Developing, implementing, and directing equipment management programs.
2. Evaluating and taking appropriate action on incidents attributed to equipment malfunctions or misuse.
3. Evaluating and selecting new equipment.
4. Establish and deliver instructional modules for clinical engineering staff as well as clinical staff on the operation of medical equipment.
5. Technology planning.
6. Quality control and technical mainstream for the operator.

1.4 Methodology

Design a framework for implementation medical equipment management system used for clinical engineering department will ensure the medical equipment work properly. The method is about how to organize and manage clinical engineering department at hospital using a software program. The project focuses on keeping data safe to avoid loss of data, inventory of medical equipment, maintenance and purchase orders.

1.5 Thesis Layout

Chapter one introduces general view of research, problem statement, objectives and methodology. Chapter two describes theoretical background.
The literature review described in chapter three. Chapter four deal with the methodology of data collection and system design. Chapter five shows results and their discussions. Chapter six includes conclusion and future recommendations.
CHAPTER TWO
Theoretical Fundamentals

2.1 Introduction

Clinical Engineering is the application of technology to health care in hospitals. The clinical engineer is a member of the health care team along with physicians, nurses and other hospital staff. Clinical engineers are responsible for developing and maintaining computer databases of medical instrumentation and equipment records and for the purchase and use of sophisticated medical instruments. They may also work with physicians to adapt instrumentation to the specific needs of the physician and the hospital. This often involves the interface of instruments with computer systems and customized software for instrument control and data acquisition and analysis. Clinical engineers are involved with the application of the latest technology to health care [4].

2.2 Evolution of Clinical Engineering

Engineers were first encouraged to enter the clinical scene during the late 1960s in response to concerns about patient safety as well as the rapid proliferation of clinical equipment, especially in academic medical centers. In the process, a new engineering discipline — clinical engineering — evolved to provide the technological support necessary to meet these new needs.

Having entered the hospital environment, routine electrical safety inspections exposed the clinical engineer to all types of patient equipment that was not being maintained properly. It soon became obvious that
electrical safety failures represented only a small part of the overall problem posed by the presence of medical equipment in the clinical environment. The equipment was neither totally understood nor properly maintained. Simple visual inspections often revealed broken knobs, frayed wires, and even evidence of liquid spills. Investigating further, it was found that many devices did not perform in accordance with manufacturers’ specifications and were not maintained in accordance with manufacturers’ recommendations.

In short, electrical safety problems were only the tip of the iceberg. The entrance of clinical engineers into the hospital environment changed these conditions for the better. By the mid-1970s, complete performance inspections before and after use became the norm, and sensible inspection procedures were developed. In the process, clinical engineering departments became the logical support center for all medical technologies and became responsible for all the biomedical instruments and systems used in hospitals, the training of medical personnel in equipment use and safety, and the design, selection, and use of technology to deliver safe and effective health care.

With increased involvement in many facets of hospital/clinic activities, clinical engineers now play a multifaceted role (Figure 2.1). They must interface successfully with many “clients,” including clinical staff, hospital administrators, regulatory agencies, etc., to ensure that the medical equipment within the hospital is used safely and effectively. Today, hospitals that have established centralized clinical engineering departments to meet these responsibilities use clinical engineers to provide
the hospital administration with an objective option of equipment function, purchase, application, overall system analysis, and preventive maintenance Policies.

Some hospital administrators have learned that with the in-house availability of such talent and expertise, the hospital is in a far better position to make more effective use of its technological resources. By providing health professionals with needed assurance of safety, reliability, and efficiency in using new and innovative equipment, clinical
engineers can readily identify poor-quality and ineffective equipment. Thereby resulting in faster, more appropriate utilization of new medical equipment. Typical tasks of clinical engineers, therefore, include:

- Supervision of a hospital clinical engineering department that includes clinical engineers and biomedical equipment technicians.
- Prepurchase evaluation and planning for new medical technology
  Design, modification, or repair of sophisticated medical instruments or systems.
- Cost-effective management of a medical equipment calibration and repair service.
- Inspection of all incoming equipment and medical equipment inventory control
- Coordination of outside engineering and technical services performed by vendors and training of medical personnel in the safe and effective use of medical devices and systems [1].

2.3 Clinical Engineering Programs

In many hospitals, administrators have established clinical engineering Departments to manage effectively all the technological resources, especially those relating to medical equipment, that are necessary for providing patient care. The primary objective of these departments is to provide a broad-based engineering program that addresses all aspects of medical instrumentation and systems support.
Figure 2.2: Illustrates the organizational chart of the medical support services division of a typical major medical facility.

Note that within this organizational structure, the director of clinical engineering reports directly to the vice-president of medical support services. This administrative relationship is extremely important because it recognizes the important role clinical engineering departments play in delivering quality care. It should be noted, however, that in other common organizational structures, clinical engineering services may fall under the category of “facilities,” “materials management,” or even just support services.” Clinical engineers also can work directly with clinical
departments, thereby bypassing much of the hospital hierarchy. In this situation, clinical departments can offer the clinical engineer both the chance for intense specialization and, at the same time, the opportunity to develop personal relationships with specific clinicians based on mutual concerns and interests.

Once the hospital administration appoints a qualified individual as director of clinical engineering, the person usually functions at the department-head level in the organizational structure of the institution and is provided with sufficient authority and resources to perform the duties efficiently and in accordance with professional norms.

The clinical engineering director, by his education and experience, acts as a manager and technical director of the clinical engineering department. The individual designs and directs the design of equipment modifications that may correct design deficiencies or enhance the clinical performance of medical equipment. The individual may also supervise the implementation of those design modifications. The education and experience that the director possesses enables him or her to analyze complex medical or laboratory equipment for purposes of defining corrective maintenance and developing appropriate preventive maintenance or performance assurance protocols. The clinical engineering director works with nursing and medical staff to analyze new medical equipment needs and participates in both the prepurchase planning process and the incoming testing process. The individual also participates in the equipment management process through involvement in the system development, implementation, maintenance, and modification processes [1].
2.3.1 Major Functions of a Clinical Engineering Department:

It should be clear from the preceding job description that clinical engineers are first and foremost engineering professionals. However, as a result of the wide-ranging scope of interrelationships within the medical setting, the duties and responsibilities of clinical engineering directors are extremely diversified. Yet a common thread is provided by the very nature of the technology they manage. Directors of clinical engineering departments are usually involved in the following core functions:

2.3.1.1 Technology Management:

Developing, implementing, and directing equipment management programs. Specific tasks include accepting and installing new equipment, establishing preventive maintenance and repair programs, and managing the inventory of medical instrumentation. Issues such as cost-effective use and quality assurance are integral parts of any technology management program. The director advises the administrator of the budgetary, personnel, space, and test equipment requirements necessary to support this equipment management program.

2.3.1.2 Risk Management:

Evaluating and taking appropriate action on incidents attributed to equipment malfunctions or misuse. For example, the clinical engineering director is responsible for summarizing the technological significance of each incident and documenting the findings of the investigation. He or she then submits a report to the appropriate hospital authority and, according to the Safe
Medical Devices Act of 1990, to the device manufacturer, the Food and Drug Administration (FDA), or both.

2.3.1.3 Technology Assessment:
Evaluating and selecting new equipment. The director must be proactive in the evaluation of new requests for capital equipment expenditures, providing hospital administrators and clinical staff with an in-depth appraisal of the benefits/advantages of candidate equipment. Furthermore, the process of technology assessment for all equipment used in the hospital should be an ongoing activity.

2.3.1.4 Facilities Design and Project Management:
Assisting in the design of new or renovated clinical facilities that house specific medical technologies. This includes operating rooms, imaging facilities, and radiology treatment.

2.3.1.5 Training:
Establish and deliver instructional modules for clinical engineering staff as well as clinical staff on the operation of medical equipment. In the future, it is anticipated that clinical engineering departments will provide assistance in the application and management of many other technologies that support Patient care, including computer support, telecommunications, and facilities operations.

Training and development of staff is an essential element of Clinical Engineering Services, not an optional extra. As such this must be taken into account when planning any increase in workload or reconfiguration of service.
Responsibility for training must be undertaken by a fully supported, designated senior grade clinical engineering. Utilize available resources to achieve the training and development programs for beginners. Highly appreciate of all acquired knowledge and engineering skills and talents [1].

2.4 Elements of the medical equipment program:

It can be seen that maintenance and repair is just one element. To make the whole cycle work properly, a number of different inputs are required.

![Diagram of medical equipment program](image)

Figure 2.3: Equipment’s life cycle

It can be seen that maintenance and repair is just one element. To make the whole cycle work properly, a number of different inputs are require [5].
2.4.1 Medical Equipment Management Plan:

The Medical Equipment Management Program is described in this management plan. The MEMP describes the procedures and controls in place to minimize the potential harm that any patients, staff, and other people coming to the facilities of system/hospital name might experience.

2.4.2 Selection and Acquisition of Equipment:

Biomedical Engineering assists, advises, and coordinates ad-hoc advisory group activities for product selection and standardization. This includes the pre-purchase evaluation of medical equipment involving nursing, technical and administrative personnel that helps in choosing safe, effective and serviceable medical equipment. Training requirements are identified at this time. The department manager is responsible for the coordination of all training of their staff.

2.4.3 Criteria and Inventory:

The Director of the Biomedical Engineering department is responsible for the development of criteria used to identify risks associated with medical equipment. The criteria are used to evaluate risks related to the function of medical equipment, physical risks related to the use of equipment, and any history of patient safety issues related to the use of the equipment. The director of the biomedical engineering department is responsible for assuring that all medical equipment is screened at the time of commissioning. The screening procedure is applied, as appropriate, to
loaner equipment, demonstration equipment, and equipment owned by physicians or other qualified individuals that is used as part of the care or treatment of a patient in any service of system/hospital name.

2.4.4 Maintenance Strategies:

The Director of the Biomedical Technology Services uses manufacturer recommendations, applicable codes and standards, accreditation requirements, and local or hospital experience to determine the appropriate maintenance strategy for assuring safety and maximizing equipment availability and service life. The strategies may include predictive maintenance, reliability-centered maintenance, interval-based inspections, corrective maintenance, or metered maintenance to ensure reliable performance.

2.4.5 Inspection, Testing, and Maintenance Intervals:

The Director of the Biomedical Technology Services uses manufacturer recommendations, risk levels, and hospital experience to determine the appropriate maintenance intervals for assuring safety and maximizing equipment availability and service life.

A computerized maintenance management system is used to schedule and track timely completion of scheduled maintenance and service activities.

The Director of the Biomedical Technology Services is responsible for assuring that the rate of timely completion of scheduled maintenance and other service activities meets regulatory and accreditation requirements.
2.4.6 Management of Medical Equipment Hazard Notices and Recalls:

The director of biomedical technology services coordinates the management of medical equipment hazard notices and recalls. The steps in the management process include:

1. Routing of all medical equipment hazard and recall notices to the responsible Biomedical Technology Services staff.
2. Logging of all hazard and recall notices determined to apply to equipment in use or storage in any location operated by Baylor University Medical Center Facilities.
3. Generation and circulation of an internal hazard and recall notice tracking sheet to all appropriate Biomedical Technology Services staff with instructions addressing how to respond to the hazard or recall notice.
4. Tracking of circulated notices to assure timely completion of activities required to eliminate or manage the issues addressed by the hazard or recall notice.
5. As appropriate, routine reports of any actions taken to address published hazard and recall notices related to medical equipment.

The Risk Management Coordinator and the Director of Biomedical Technology Services are responsible for the Safe Medical Devices Act (SMDA) Reporting process. Information about reportable events is processed through the incident reporting process. Internally, the Risk Manager applies the Root Cause Analysis (RCA) process to all SMDA events. The findings of the RCA are used to update or develop procedures and controls, make changes in the environment, or
provide additional education and training to eliminate or reduce the risks that led to the reportable event.

2.4.7 Emergency Procedures:

The Biomedical Technology Services staff and appropriate clinical care givers collaborate to identify the appropriate amount of back-up equipment during the evaluation/selection process of choosing the medical equipment. In the event of a medical equipment failure:

A. The clinical department personnel will take appropriate clinical intervention until replacement equipment is available or the medical equipment is repaired.

B. The clinical department will contact Biomedical Technology Services to see if back-up equipment is available. If equipment is not available, contact Supply Chain Management for help.

C. The clinical department will contact Biomedical Technology Services for repair of medical equipment.[6]

2.5 Computerized maintenance management system (CMMS):

Computerized maintenance management systems (CMMS) are tools for Planning and scheduling equipment maintenance and asset management to meet the needs of modern plants and facilities. Using information about system components, CMMS software schedules maintenance, repairs, and inspections of such components. CMMS software notifies operations personnel when maintenance or other action is necessary. One example of CMMS software is the MAXIMO system, offered by Project Software and Development [7].
The term CMMS software stands for computerized maintenance management system. These systems keep track of maintenance activities through a work order system that is facilitated by a local network or the internet, and are used by maintenance and facilities departments across all industries [8].

Evaluation of indicators requires the collection, storage, and analysis of data from which the indicators can be derived. Many Computerized Maintenance Management Systems (CMMS) are handy available to determine the most common data elements used. Indeed, most of the high-end software systems have more data elements than many clinical engineering departments are willing to collect. This is especially important if the data will later be used for comparisons with other organizations. Different departments often have different definitions for the same data element. It is crucial that the data collected be accurate and complete. It makes no conceptual difference if the database is maintained on paper or using computers. Computers and their databases are ubiquitous and so much easier to use that usually more data elements are collected when computerized systems are used.

A computerized maintenance management system (CMMS) is a software package designed to maintain a computer database for an organization’s Maintenance operations and human resources functions. This data is intended to help the effectiveness of maintenance workers, the quality of management decisions and the verification of regulatory compliance.

CMMS software packages are nearly the same as computer aided facility management packages, which are also called facility management
This term is also known as Enterprise Asset Management and Computerized Maintenance Management Information System (CMMIS). CMMS packages come in a wide range of capabilities and prices. Typically the software addresses the following:

1. Work Orders and Descriptions: Varying techniques are used to report when an inspection, automatic preventive maintenance, meter readings or repair job is to be done. Related recorded data may include reserving materials, assigning personnel, scheduling work, tracking equipment downtimes, future recommendation actions and problem causal factors.

2. Managing Inventory: Data is recorded about current inventory and inventory levels in various categories, reserving inventory for particular jobs and purchasing and tracking inventory.

3. Managing Assets: Typically recorded data is intended to aid management or maintenance workers and may include equipment specifications, purchase dates, anticipated lifetime, required spare parts, service contracts and history and warranty information. Metrics may also be generated to measure the effectiveness of the asset management program.

4. Safety: Data is recorded on safety permits and documenting safety requirements [9].
CHAPTER THREE

Literature Review

In this section some of papers will be represented as the following, the research and scientific papers in common, that all work to manage the Clinical Engineering Department. We see several ways to apply it. Data analysis, HIS and programming languages which is used in the research. Microsoft Access was used that saves data is different from other technologies that use RFID technology data, SD card and network.

May see some features in the research which create work orders automatically according to a schedule or manually from service requests; record authorized uses of equipment; and track scheduled services or PMs, training, maintenance history, employee time, downtime of a device, parts inventory, purchase orders, and much more

Guo Fonda in 2014 the utility model discloses a medical equipment data acquisition hand-held machine based on an RFID technology. The hand-held machine comprises a processor, a radio frequency antenna, a radio frequency transceiver, a power supply assembly, a memory, a wireless communication device, a touch screen controller, a touch screen, a liquid crystal backlight driver, an image collector, a camera, a shell, a hand-held handle and an operation button. The radio frequency transceiver, the power supply assembly, the memory, the wireless communication device, the touch screen controller, the liquid crystal backlight driver and the image collector are connected with the processor. The liquid crystal backlight driver is connected with the touch screen. The touch screen is connected
with the touch screen controller. The radio frequency antenna is connected with the radio frequency transceiver. The camera is connected with the image collector. The hand-held handle is arranged on a lower end of a shell. The touch screen and the operation button are embedded in a front end of the shell, and the radio frequency antenna is arranged on a top of the shell. The hand-held machine provides a visual and friendly information interaction interface. A wireless data communication mode is provided. Read label information can be stored in real time through a wireless transmission mode or a SD card [10].

David Lyle Schneider et al in 2014 a medical protection safety lockout system for procedures and devices which can be integrated internally or retrofitted externally to any electronic medical equipment providing treatment or diagnostic medical care to a patient. Methods include both Patient acceptance process, verifying patient acknowledgement and medical procedure consent, and Clinician acceptance process, acknowledging patient identity and appropriate clinical procedure sign-offs. The apparatus and methods deliver reliable and trustworthy patient safeguards to electronic medical equipment [11].

Akira Masuda et al in 2013 to provide a medical equipment information management system and so forth wherein medical equipment information can be appended easily to medical equipment at a low cost while confirmation of medical equipment information such as an operation manual by a user and so forth are assured. A medical equipment information management system 1 including a medical equipment information storage medium 10 capable of storing and transmitting
medical equipment information and disposed in a packing unit 3 configured to package medical equipment 2, a medical equipment information reception block 50 configured to receive the medical equipment information transmitted from the medical equipment information storage medium, and a display unit 31 configured to display the medical equipment information received by the medical equipment information reception block, wherein the medical equipment information storage medium cannot transmit the medical equipment information when the packing unit is in a non-opened state, but is placed into a state in which it can transmit the medical equipment information if the packing unit is opened [12].

Daryl Miller in 2013 the present invention employs a system and method to allow for connectivity of a plurality of medical devices in a health care setting. The present invention utilizes a device server which may connect the plurality of medical devices to a hospital information system. The system may identify and authenticate a medical device and provide an administrator or privileged user accessing the information received from the medical device at a remote location. It is contemplated that the system utilizes a device server to connect the plurality of medical devices to the hospital information systems [13].

Yuuji Sawanaga et al. in 2013 A medical equipment management apparatus for managing medical equipment provided in a medical facility connected to the apparatus through a network. The apparatus comprises a reception unit, a storage unit, a prediction unit, a determination unit, and an informing unit. The reception unit is configured to receive a parameter data
regarding the medical equipment more than once. The storage unit is configured to store the parameter data, and the prediction unit is configured to calculate an expectancy of the parameter data to be received in the future based on the stored parameter data. Further, the determination unit is configured to determine a level of the expectancy, and the informing unit is configured to give a notice to the medical facility through the network according to the determined level [14].

Jiang Yuanlin in 2012 The utility model relates to the field of hospital management and discloses a medical equipment location management system based on Internet of Things technology. The medical equipment location management system comprises a computer management system, medical equipment, a radio frequency identification device (RFID) system and a wireless network. The RFID system comprises an RFID label (1), a reader (2) and an antenna (3), the RFID label (1) is affiliated on the medical equipment and records information of the medical equipment, the reader (2) writes in and reads the information to the RFID label (1), and the antenna (3) transmits radio-frequency signals between the RFID label (1) and the reader (2). By means of the technical scheme of the medical equipment location management system, systematic management monitoring of all the medical equipment is carried out through the RFID system, information management automation of the medical equipment in a hospital is achieved, timely location can be conveniently called out and managed, management is perfect, and loss of the equipment is avoided [15].
David Mutai et al in 2012 the research paper evaluated the existing facilities maintenance management practices and processes in major hospitals in Kenya. The facility managers from major hospitals were interviewed on medical equipment management. The data collected from the facility managers determined their effectiveness as they managed the life cycle of the medical equipment. The results offered management the opportunity to appraise the overall maintenance program and sought improvement for increased efficiency and more effective utilization of available resources. The challenges encountered in this research included hospital’s policy and technological resources. The facility maintenance management in the public hospitals was not effective as they were ranked forty percent on their performance. The maintenance computer program was developed to improve the existing facilities maintenance management for hospitals in Kenya. The program guides the user on the causes of the fault, possible personnel to handle the fault and establishment of inventory system of medical equipment [16].

Sudhir Rewar in 2012 Medical equipment management is an important issue for safety and cost in modern hospital operation. In addition, the use of an efficient information system effectively promotes the managing performance. The system is web-based, and it integrated clinical engineering and hospital information system (HIS) components. Objective - design a framework for implementation medical equipment management system used for clinical engineering department. Method - we prospectively enrolled 100 staff (technical staff, consultant and clinical engineering department staff) during 2 April 2012 to 15 April 2012. Result - The results showed few examples in the error analysis of medical
equipment by the maintenance sub-system. There are lacks of proper communication system between CED dept. and other hospital dept (36%), outdated parts (18%), machine location identification (16%). These problem arises because absence of proper complaint system. The hospital information system can be used to improve work quality, to reduce the maintenance cost, and to promote the safety of medical device used in patients and clinical staffs. Conclusion - Through related hospital information application, it efficiently improved the operation management of medical devices immediately and continuously. Through HIS we easily manage medical equipment in different department, different location in hospital. HIS helps CED department to manage complaint system in a proper manner so they quickly done solution for a particular complaint [17].

Michael Golden in 2010 Systems and methods that include configurations of a medical device, user device and service platform are described. Embodiments may include a secure network to run medical applications that control and/or monitor the medical device. An online store may be provided for storing and distributing medical applications to the user device and medical device. A secure environment may be provided within the user device and medical device that protects the integrity of medical applications running on those devices. A service platform may provide a service that enables a medical authority to certify and monitor the medical applications. In some implementations, various third parties and the user of the user device may be allowed to manage and monitor the medical device [18].
Yadin David in 2008 appropriate deployment of technological tools contributes to improvement in the quality of healthcare delivered, the containment of cost, and better access to healthcare systems. Hospitals have been allocating significant portion of their resources to procuring and managing capital assets; they are continuously faced with demands for new biomedical technology while asked to manage existing inventory for which they are not well prepared. To effectively manage their investments, hospitals are developing medical technology management programs that need expertise and planning methodology for safe and efficient deployment of healthcare technological tools. Clinical engineers are practitioners that can lead such programs and deliver technological solutions based on carefully determined needs and specified set of organization objectives and abilities. The successful practice of clinical engineering is dependent on the ability of these practitioners to transfer knowledge from the engineering and life sciences to the support of clinical applications. As rapid changes in the complexity and variety of technological tools and in the measurement of patient care outcomes taking place, it is best to facilitate transfer of such knowledge having well defined body of knowledge. This can be accomplished only when the goals of the profession are clearly described and uniformly accepted accommodating profession vision and commitment. Such a commitment must include the promotion of safe and effective application of science and technology in patient care and on the acceptance of professional accountability demonstrable by the achievement of competency recognition by national professional certification program.

To be ready, clinical engineers must participate in continuing education activities and maintain wide level of expertise, demonstrate ability for
leading and effectively executing complex projects and functions, and be accountable for maintaining safe technological tools/systems used in the patient environment. As systems complexity and integration continues to increase, now is the time to demonstrate that the required competencies do contribute to desired outcomes [19].
CHAPTER FOUR
Methodology and Design

4.1 Introduction

The main concept of medical equipment management program is summarize in six steps as shown in figure (4.1). Each step’s output can be input for next step.

Figure 4.1: The main concept of medical equipment management program
4.1.1 Data collection

Collecting data are depending on the development of the previous studies that fit with the clinical engineering department in hospitals and health institutions.

The data was collected through guided interviews, documentation review and archival records. Reviews were conducted to assess four key elements: service performance, supervision, training and orientation. The findings of the research described the status of facilities maintenance management in the hospitals under study to be having a good planning and management with all essential requirements and compliance with regulation. However, the audit assessment was not able to develop and implement comprehensive and systematic policies, plan and procedures of facilities management through a maintenance management program. This is because the main objective of the research was only to identify the maturity level of the maintenance organization in specific hospitals with regard to the effectiveness of their management of facility engineering maintenance services. The result from the research suggested that the maintenance organization in the case study hospitals had still not realized the importance and effective maintenance management. It was apparent from the research findings that the maintenance organization had not made much effort to accomplish their roles and responsibilities towards successful implementation of facility engineering maintenance services.
4.1.2 Planned management system

The Medical Equipment Management Plan defines the mechanisms for interaction and oversight of the medical equipment used in the diagnosis, treatment, and monitoring of patients. The related policies and procedures govern activities from selection and acquisition to incoming inspection and maintenance of medical equipment. The mission is to ensure that equipment used in patient care is safe, available, accurate, and affordable.

Medical equipment brings along with it associated benefits and problems. The problem that draws the most attention is maintenance. Lack of a maintenance policy can result in no advance planning for maintenance budgets and thus no availability of spares and accessories.

Planned management system needs effective maintenance strategy. It is essential that we plan the resources required for maintenance. Planning will need to be made for both repair work and also for planned preventive maintenance. The following will also promote effective maintenance:

- Inventory and documentation:
  A proper entry should be made in the inventory register. The inventory record should contain the serial number and date of receipt as well as date of completed inspection.

- Equipment history record:
  There should be an equipment history record sheet to track the performance of the equipment.
  This sheet should note down the date of installation and commissioning, preventive as well as corrective maintenance records.
• Maintenance

Proper maintenance of medical equipment is essential to obtain sustained benefits and to preserve capital investment. Medical equipment must be maintained in working order and periodically calibrated for effectiveness and accuracy. There are two types of maintenance:

• Corrective Maintenance (or Repair)

This is done to take corrective action in the event of a breakdown of the equipment. The equipment is returned repaired and calibrated.

• Planned (or Scheduled) Preventive Maintenance

This work is done in a planned way before repair is required and the scheduled time for the work circulated well in advance. It involves cleaning, regular function / safety tests and makes sure that any problems are picked up while they are still small.

The choice of approach for Preventive and Corrective Maintenance depends on the complexity of equipment Maintenance by in-house trained technicians

• Condemnation of old and obsolete equipment

The life cycle of medical equipment will vary from 5-10 years. If the equipment is declared obsolete by the vendor it may not be possible to get spare parts. Even if the parts are available it can become too expensive to obtain them and the equipment is no longer economical to repair.

Condemnation of equipment should be well planned and the necessary steps should be taken in advance to arrange replacement.
• In procurement it should be made mandatory for the vendors to provide the following:
  • Training to technicians and operators.
  • Providing user / operating manuals.
  • Providing service / maintenance manuals
• Receipt and incoming inspection
  Incoming equipment should be carefully checked for possible shipment damages; compliance with specifications in the purchase order; and delivery of accessories, spare parts and operating and service manuals.
• Installation and final acceptance
  Installation should be done by the vendor and training should be provided at this stage to the user as well as to the maintenance technicians.

### 4.1.3 System software

The system designed by using Microsoft Access which used the database.

Microsoft Access, also known as Microsoft Office Access, is a database management system from Microsoft that combines the relational Microsoft Jet Database Engine with a graphical user interface and software-development tools. It is a member of the Microsoft Office suite of applications, included in the Professional and higher editions or sold separately.
Microsoft Access stores data in its own format based on the Access Jet Database Engine. It can also import or link directly to data stored in other applications and databases. [20]

Software developers and data architects can use Microsoft Access to develop application software, and "power users" can use it to build software applications. Like other Office applications, Access is supported by Visual Basic for Applications, an object-oriented programming language that can reference a variety of objects including DAO (Data Access Objects), ActiveX Data Objects, and many other ActiveX components. Visual objects used in forms and reports expose their methods and properties in the VBA programming environment, and VBA code modules may declare and call Windows operating-system functions.

Microsoft access uses its own database storage file, it's may be used as the 'front-end' of a program while other products act as the 'back-end' tables, such as Microsoft SQL Server and non-Microsoft products such as Oracle and Sybase. Multiple backend sources can be used by a Microsoft Access Jet Database (accdb and mdb formats). Similarly, some applications such as Visual Basic, ASP.NET, or Visual Studio .NET will use the Microsoft Access database format for its tables and queries. Microsoft Access may also be part of a more complex solution, where it may be integrated with other technologies such as Microsoft Excel, Microsoft Outlook, Microsoft Word, Microsoft PowerPoint and ActiveX Controls.
Database Structure: A database is a computer program for storing information in an easily retrievable form. Also a database is a collection of components that work together; these components are called objects:

- **Tables** are the most important part of a database. They contain the data. Tables present the data as a datasheet with the data arranged in rows (records) and columns (fields). You can edit data directly in a table and add or delete records. The data can also be sorted and filtered in this view.
- **Queries** are commands to the database that retrieve data matching criteria you define. With a query, you can view or manipulate a selected subset of the data stored in a single table or multiple related tables. Reports and forms access data stored in tables by using queries to filter what is displayed. Queries look similar to tables, as both objects display raw data in a grid.
- **Reports** are graphical objects that present data in a formatted layout. This is useful for displaying data in an organized manner, and for printing. Reports can also group and sort data, perform and display calculations, and produce charts. Because a report is a graphical object, you have a great deal of design control over the formatting and layout of elements that are displayed.
- **Forms** are graphical objects that act as an interface between a user and the tables where data is stored. With forms you can view, edit, input, and delete records stored in tables. Forms also create a buffer to prevent users from altering the design of tables while accessing data. You can also create forms that have no data source but which perform other tasks. Like reports, forms give you wide control over the graphical design and presentation of form elements.
A Page is a special type of web page designed for viewing and working with data from the Internet. This Access feature is beyond the scope of these tutorials.

A Macro is a sequence of instructions which can be carried out with a single click of the mouse button on a button in a toolbar or by pressing a key or combination of keys on the keyboard.

A Module is a collection of programming procedures designed to give Programmer control over the Access database look and feel [21]

4.1.4 Implementation:

4.1.4.1 Installation:

Many common problems with maintenance system can be avoided if it is properly installed.

Before installing the system, a system administrator is assigned who is responsible for the technical maintenance of the system and for managing data security.

Installation and Training Services ensure smooth set-up and training for your new system.

The software can be implemented as a complete system, by individual modules, by equipment type or by location. This is the decision of the clinical engineering department and will depend on the resources available. The software is installed on the health facility server or on the individual user’s personal computer. All other hardware devices such as line printers and scanners must also be installed and configured.
4.1.4.2 Calibration:

Whenever the system is installed, it is necessary to execute the calibration procedure (setup) before connecting it to the service. Calibration is nothing more than the comparison of the system or software performance to a known standard of accuracy. Calibration status of the system, the date of calibration, the next calibration date and the identification of person performing calibration should be readily available.

4.1.5 Evaluation:

The evaluation was an integral part of the system development. It has been accomplished in three levels including: testing, verification and validation. The scope was to ensure the system functionality. Testing procedures involved internal evaluators, as well as, professionals in software evaluation, having knowledge of the system structure. Testing goal was to determine the proper functionality of the system, monitoring of problems, related to database management, weak points in the software packages. Moreover the integrated system has been distributed for verification to a number of external end-users – the preventive maintenance system. Feedback comments have been collected, analyzed and consequently improvements were introduced. The installation of the system includes training and education of the preventive maintenance system staff, and technical support.

Planned, ongoing evaluations help identify what aspects of the program. They also identify what is working successfully and should continue into
the future. Data collected through evaluations help determine the costs and benefits of preventive Maintenance practices.

Engineers may evaluate preventive maintenance in any of several ways, some of which are set measurable, formal goals for the program and measure progress toward meeting them. Also Analyze work orders to mark progress in the preventive maintenance program.

Set standards for various tasks performed by employees. Once employees understand the standards, engineer periodically inspect employees’ completed work to measure how well it meets the standards.

### 4.1.6 Operate and training:

After installed the software and must be ensure that work properly, then the next stage is training the technical staff.

The technical staff and the clinical engineering department manager have dual responsibility for ensuring that the technical personnel as well as the clinical users are informed, trained and versed on their specific responsibilities. Training and education is not a one-time activity but a continual process. Enabling staff to see that learning is important and a constant feature of their job will improve reliability and success in future problem solving.

Training of technical personnel can be provided inside the health-care organization:

A. For operating the equipment – to be given by Manufacturer/Supplier periodically and preferably to be mentioned in Tender Enquiry Document.
B. To deal with routine maintenance and repairs must use of tool kit, knowledge about common and recurrent causes of failure of the equipment and how to rectify minor causes of failure and calibration of the equipment. Training can take place outside the organization:
A. For operating the equipment (if required)
B. To deal with routine maintenance

The methods of training suggested above, progress from the least expensive to the most expensive to implement. So depending on hospital resources, local availability of information sources and the ability to coordinate with other hospitals who might have technicians to train as well, the hospital can choose a methodology that best matches their resources. It should be noted however that the most effective training methods for sophisticated equipment are the more expensive options.

4.2 Design

The design describes the CE management software. It describes how to create system and maintenance plan either corrective or preventive maintenance based on usage and time respectively, and organize the medical devices data by using the inventory processes, that use to add the new devices and archive the scraped, and also this software provide adding user and managing their access levels and a get advice of buying a new device.
4.2.1 Inventory

In the inventory, data in the form is taken from interviews in hospitals and how to insert a new medical device in the system. It needed by clinical engineer in purchase, warranty and maintenance. Each device will have an ID number. When a problem occurs cannot be solved for the device is deleted and put it in archive.

![Image of the Devise Details form](image.png)

Figure 4.2: Design of new device form
4.2.2 Request

Requests form design depends on the device id number and the person who responded to the request with a brief description of the problem to save in system.
4.2.3 Periodic preventive maintenance (PPM)

This report is a semi-annual examination of medical devices from the day of entry. Report shows the device with sheets entrance in advance with the system is a check list to evaluate equipment.
Figure 4.5: Design of ppm report

Figure 4.6: ppm sheet
4.2.4 Troubleshooting

This report is to help the clinical engineer in keeping data on the problem cause and the way to solve it, with the possibility of attached files belonging to the specified device.

![Troubleshoot Details](image)

Figure 4.7: Design of troubleshooting form

4.2.5 Purchase

The design of this report is based on requests, price of medical devices and manufacturer’s. From interviews information, this report provides information to help in the selection of a new device.
4.2.6 Report

The CE department depends on reports in a lot of meetings to determine the workflow and requirements of department. Based on interviews information taken from hospitals designed a number of reports in system that help to manage the CE Department.
4.2.7 Setting

This form is to insert user data and password for security. Also identify user access level.

Figure 4.9: Design of report window

Figure 4.10: Design of user details report
CHAPTER FIVE
Results and Discussion

5.1 Installing the CE management software

In the compatible disc (CD) comes with the research book, file will be found (CNMP setup), ‘CNMP setup’ is the actual software. Double click on ‘setup _x32 file in the CD directory the following window will appear click on the check box then click on continue.

![Figure5.1: Microsoft Access runtime Setup](image)

The installation process will start immediately. A window will appear press next.
The installer will require a file destination it’s highly recommended to remain unchanged as shown in figure (5.3) bellow.

The process now is straightforward press next until it shows install then click it wait until it finishes then click on finish.
After a while the clinical engineering management software will open and it will take you immediately to the login screen.

Now the clinical engineering management software system software is ready for your data management.
5.2 Login

Login is a process by which individual access to the software is controlled by identifying and authenticating the user through the credentials presented by the software’s Administrator. This form allows user to access the system by entering the user name and the password. This system identifies users by three access levels:

1. Administrator.
2. Engineer.
3. Technicians.

And the system already comes with a predefined user with administrator privileges “User name: Fatima, Password: Fatima”.

Figure 5.6: Login screen after fill

5.3 The Main menu:

The Main menu provides a platform that the user can interact with. This window may differ for users upon their access level which is Administrator, Engineer, and Technician. It’s consist of: inventory items
form, requests form, Troubleshooting form, PPM form, purchase form, Reports form, setting form (Administrator-only) and logout.

![Main Menu](image)

**Figure 5.7: The Main menu**

**5.4 Inventory item:**

Inventory item window allows the user to add new devices and reviewing the list of devices stored in the system and archives that deleted scrape devices. It also consists of reports of all devices and all archived.
5.4.1 Add new device steps:

Click on new device button, a new blank window will open containing the necessary field for including the device.

Figure 5.9: New device window
Then, fill the device data as follow

![Device Details](image)

**Figure 5.10: New device (filled) window**

Next step is click on save and close button to save the inputs

### 5.4.2 Archived steps and delete a device

Deleting is only available for the administrator to overcome security issues. Click on archive button of a specific device. A new window will open obtaining the device’s details.

![Archive Devices](image)

**Figure 5.11: Archive devices window**
Click on archive button to archive the device in the database and delete it from inventory list as follow

![Archive Devices window](image)

**Figure 5.12: Archive Devices window**

### 5.4.3 All Devices

This window illustrates all devices that entered to the system by user as figure (5.13) below.

![All devices window](image)

**Figure 5.13: All devices window**
5.4.4 All archive:

This window illustrates all devices that entered to the system by user as shown in figure (5.14) bellow.

![All archive window]

Figure 5.14: All archive window

5.5 Requests:

This option illustrates the requests that received from the different hospital departments (ICU, ER, OP ..... etc.) and that by using local institution network or other communication ways.
5.5.1 New request

Press on new request button to send new request and describe the devices problem by filling the request as below.

![Request window](image1)

![New request detail window](image2)
After fill the request data as follow click on save and close button to save the inputs.

![Request Details](image)

Figure 5.17: Request details filled window

### 5.5.2 All request:

This window shows all requests that received to the system as figure (5.18) bellow
5.6 Troubleshooting:

This window allows the user to access the troubleshooting process of specific selected device see figure (5.19). Also there is attachment option that allow user to upload the specific device troubleshooting from manufacture manual, and can search by device name on it.
By pressing on troubleshoot button can add problem and there solution

![Troubleshoot Window](image)

Figure 5.20: Cause and solution of the selected problem

5.7 Periodic preventive maintenance (PPM)

This window allows user to access to the inspection process of all devices. Shows in figure (5.21) this option notifies user to the device need to periodic maintenance every (six month).
5.8 Purchase advice

The purchase window introduce advice about buying advice that by search about device wont to buy. showing all manufactures in hospital for this device, cost and number of requested since device reserved.
Figure 5.22: Purchase window
Search about device (one from inventors list) can see the next figure

Figure 5.23: Result of purchase advice
5.9 Reports:

The report window handles the process of querying devices database to generate a readable report which illustrated in Figure (5.24).

Figure 5.24: All reports window

This form consists of two types of report:

5.9.1 Devices report form:

Which generate all devices report, all requests and all troubleshooting it’s accessed by clicking on button and it can further be printed.
5.9.2 Graphic form:

Which generate reports of all the devices per request in the system, it’s accessed by button.

Figure 5.25 Report form

Figure 5.26: graphic report form
5.10 Setting window:

This window allows you to manage and create new users. This form is only administrator accessible.

Figure 5.27: Main user’s setting window

You can add a new user by clicking on new user button. A new window will appear requiring the new user information.

Figure 5.28: New user window
Fill the fields on both contact user and note fields respectively.

![User Details](image)

Figure 5.29: Adding new user

Click on save button to save the new user into users table.

This User window grants authority user levels for users to interact with the system based on three levels:

1. Administrator Level:
   Allows full manipulation on the system and full access to users editing window

2. Engineer Level:
   Same as the Administrator level but has a restricted editing authority on Log Book window, and no access to the Users window.

3. Technician Level:
This has restricted editing authority to all the system (cannot add or edit devices, cannot edit log book, no access to the Users window)

Figure 5.30: All user window

5.11 Discussion

The result demonstrates CE system is a stand-alone database program. It is designed as a complete medical equipment management system. It uses a risk-based approach using equipment history, in order to focus the inspection on devices that most need it. The difference from the originally proposed system, it is can fit with any system based on its own database there is flexible for modifications and enhancement a successful equipment control program is needed to optimize the selection, procurement, use and maintenance of electro-medical instrumentation in the hospital.
As the CE program becomes effective, the reliability of the equipment increases, and the users gain confidence in the equipment they have less difficulty operating it, and they are sure of the calibration. The advantages expected from the system will be evaluated after its installation and use in a hospital. Further requirements of the end user will be considered while the complete medical technology management project evolves. The program evaluation describes CE documentations and operating procedure. And looks at the quality of existing data and record keeping that would result in significant cost reduction to real properly maintenance and repair costs.

Through systematic data collection in each stage (such as purchase, contract, repair, and maintenance), it provides useful information to advance the management ability in CED more effectively and efficiently. With regard to how to run data into useful information, however, the data format and operating interface are very important. They will influence the information whether is accurate and comprehensive. Data quality initiatives can help to insure the accuracy of clinical/biomedical engineering data. Some important key fields in designing database may be considered. The cost data is also important for modern enterprise, so the related cost value like purchase, installation, training, consumables, operating, maintenance, contract, and disposal needs to be involved. Other useful data could include: warranty, location, other contractor agencies, scheduled maintenance due dates, and intervals.
 CHAPTER SIX

Conclusion and Recommendation

6.1 Conclusion

An effective CE management program is designed to manage the CE department and maintain equipment in good operating condition, and organize the maintenance process by reducing the incidence of failure through inspection designed to detect potential problems before they become reality.

Medical equipment has become an important component of modern health services. The growth in capabilities to manage or maintain medical equipment has lagged far behind the rate of deployment of equipment. In addition to the traditional operation management, the patient safety, operation performance in cost/efficient analysis, and risk evaluation and control are the important issues for using medical equipment in hospital. A framework of medical equipment management system has been proposed in the paper for assisting in-house CE department early to confront the potential risk. Through computer program we easily manage medical equipment in different departments, different locations in hospital. Computer program helps CE department to manage complaint system in a proper manner so they quickly done solution for a particular complaint. Implementation of the computer program improved the managing and organizing the biomedical department by detecting the faults in the shortest duration, to reduce the time for repair of equipment and buying it because the information required will be accessed immediately. The facility maintenance management practices and the quality of patient care
will be improved. And also reduced paperwork and loss of data in the maintenance management.

Good management of medical equipment which includes selection, purchase, installation and maintenance are important for ensuring continued readiness of the service, positive impact on the safety and Effectiveness of health services. It increases the lifetime of the equipment and provides information essential for equipment management.

6.2 Recommendation

1. Local network in hospital or health institution must be providing to receive the request in case of problems.
2. Connect between hospital departments using software to automate reports, data, and results exchange.
3. The software program can be extended to add more features, abilities and enhancing the software security.
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