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Sudan University of Science and Technology

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DESIGN AND IMPLEMENTATION OF EQUIPMENT CONTROL PROGRAM

تصميم وتنفيذ برنامج تحكم معدات

A Thesis Submitted in partial fulfillment of the requirementforthe M.Sc. Degree in Biomedical Engineering

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الآية

(وَقُلِ اعْمَلُوا فَسَيَرَى اللَّهُ عَمَلَكُمْ وَرَسُولُهُ وَالْمُؤْمِنُونَ ۖ وَسَتُرَدُّونَ إِلَىٰ عَالِمِ الْغَيْبِ وَالشَّهَادَةِ فَيُنَبِّئُكُم بِمَا كُنتُمْ تَعْمَلُونَ)

{سورةالتوبة: الآية 105}

صدق الله العظيم

DEDICATION

I dedicate my work to a number of people without whom this thesis might not have been written, and to whom I am greatly indebted.

To my family and many friends who have supported me throughout the process.

A special feeling of gratitude to my parents, my sisters and my brothers, I will always appreciate all they have done.

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Firstly I wish to thank my hospital members who were more than generous with their expertise and precious time.

I would like to acknowledge and thank many biomedical engineers in many hospitals for allowing me to conduct my project and providing any assistance requested.

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Finally I would like to thank all members of biomedical engineering department for their unconditional support, patience, optimism and advice was more valuable than I could ever imagine.

ABBREVIATIONS

ASP	Active Server Pages.
CDRH	Center for Devices and Radiological Health.
CPS	Cyber-Physical Systems.
CFR	Code of Federal Regulations.
FDA	Food and Drug Administration.
FD&C	Food, Drug and Cosmetic.
GMP	Good Manufacturing Practices.
HTML	Hyper Text Markup Language.
HTTP	Hyper Text Transfer Protocol.
LAN	Local Area Network.
MEMP	Medical Equipment Management Program.
MVC	Model- View- Controller.
QS	Quality System.
QA	Quality Assurance.
SOP's	Standard Operating Procedures.
SPSS	Statistical Package for the Social Sciences.
SQL	Structured Query Language.
UL	Unordered List.
UI	User Interface.
URL	Uniform Resource Locator.

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ABSTRACT

Tracing of the lifecycle of the medical devices affects in the health care facility, the medical devices system is very important to control the processes in the hospital, whichrelated with the medical devices and provide a good health services for the patient.

The objective of this project is to design and implement a computerized system to process the information for medical devices in centralized source, which help physicians, nurses and the staff in their work.

This work has been using the SQL server 2012 to create the data base, ASP.net MVC5 in architectural pattern and HTML as user interface, it contains an interface to enter the program and other to deal with the system options.

The proposed system performs the data entry of all related information for medical devices as master data like (sort of device, classification, sub classification, accessories, spare parts, companies, departments, properties and reports) or sub-master data like (add device, preventive procedures, maintenance and troubleshoot).In one minute the program can enter a number of devices information and printed as a report.

The equipment control program implemented in Alrawda hospital, The data which applied in the program are becomes a database of equipment, then the results of them are proposed as reports when the need (weekly, monthly or annually) to solve problems and detected defects that hinder work flow, and that offers the best improvement in the hospital, The results obtained after the implementation of the program are very acceptable.

المستخلص

تتبع دورة حياة الأجهزة الطبية يؤثر في مرافق الرعاية الصحية ونظام التحكم بالأجهزه الطبية مهم جدا" في ضبط العمليات بالمستشفى وتوفير الخدمات الصحيه الجيده للمريض.

الهدف من هذا المشروع هو تصميم وتنفيذ نظام محوسب لمعالجة المعلومات للأجهزة الطبيه في مصدر مركزي والتي تساعد الأطباء والممرضين والموظفين في عملهم.

صمم هذا المشروع بإستخدام (SQL server 2012) لإنشاء قاعدة البيانات وهيكل البرنامج الرئيسي باستخدام (ASP.NET MVC5) و(HTML) لواجهة المستخدم والتي تحوي واجهتين واحده للدخول للنظام والأخرى لتشغيله.

النظام المقترح يقوم بإدخال جميع المعلومات ذات الصله بالأجهزه الطبيه كبيانات رئيسيه مثل (نوع الجهاز أو تصنيفه أوقطع إكسسواراتأوقطع غيار أوالأقسام أوخصائص الأجهزه أوالتقارير) أو بيانات فرعيه مثل (إضافة جهاز أوالصيانه أوإستكشاف الأخطاء وإصلاحها). يتمكن البرنامج في دقيقه من إدخال عدد من معلومات الأجهزه وإستخراجها كتقرير.

برنامج التحكم تم تنفيذه في مستشفى الروضه, البيانات التي طبقت في هذا البرنامج تصبح هي قاعدة بيانات بها معلومات الأجهزه, وتعرض النتائج كتقارير (أسبوعية أوشهرية أوسنوية) عند الحاجة لحل المشاكل والكشف عن العيوب التي تعيق سير العمل مما يطور الوضع الصحي بالمستشفى, النتائج التي تم التحصل عليها بعد تنفيذ البرنامج مقبوله جد".

CHAPTER ONE

1. INTRODUCTION

1.1. General view:

Medical design control is an application of technology to health care in hospitals. It can be a part of the health care system involves the interface of instruments with computer systems to health care team.

The computer database records for devices (control program) had been a critical component of health care, as it enables clinical engineers to monitor the situation of instruments in hospital and provide an appropriate solution for any problem that facilitate the quality management of medical equipment and helps to ensure that the services are provided in a safe and effective way.

The first step in recording the database is to determine what items are to be collected and to create the computer databases records. The records are a working document that is regularly checked and updated to accurately reflect the status. When used appropriately, the records serve as an important and powerful tool to improve management of many key aspects of health-care.

The primary aim is to collect any materials or instruments that related to the biomedical engineering field in a main source, as Medical devices that contains instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose.

Medical equipment that contains Medical devices requiring calibration, maintenance, repair, user training, and decommissioning – activities usually managed by clinical engineers and any Medical equipment that used for a specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; all of those can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment , medical equipment excludes implantable, disposable or single-use medical devices.

1.2. Problem statement:

Document control is an essential requirement in regulatory environments, touching all quality processes in hospital. That not available in our most health facilities. Clinical engineer couldn't found centralized location for all documents they need about devises in all hospital departments.

Building software that collects information in one source can be a good solution. It is connected to other processes for a seamless quality management. Document control software automate the entire lifecycle of medical equipment's, it reduces risks and difficulty and also increases efficiency to accelerate time in solving problems and maintenance.

1.3. Objectives:

The objectives of study are divided to general and specific objectives.

1.3.1. General objective:

- Enhance the flow of work to the clinical engineer in the hospital, which will be able to go to a single centralized location for all documents they need.
- High accuracy in detecting any defects or needs.
- Provides useful information to support health care.

- Very quick and easy reaching to all data that related to anything concerned to the Medical equipment.

1.3.2. Specific objective:

- Designing computerized management program.
- Implementing design control for medical devices contained in the quality system of specific hospital.

1.4. Methodology:

- Data collection in study will be collected from text books, references and web sites.
- Visits the medical facilities that help in field of study, for example the health care team in the hospital will participate during the study period by interviews and questioners.
- Data analysisto facilitate development of program.
- Design the program to control equipment in hospital, with the needed parameters.
- Implementation of developed program in selected hospital.

1.5. Thesis layout:

Chapter one discusses a brief general view, problem statement, thesis objectives, and an overview of methodology, Chapter two will discussa theoretical fundamental about the medical devices, quality management system, medical devices software and design control program, Chapter three discusses the related work of previous studies and a literature reviews, Chapter four discusses and describes the methodology that was applied for building the program and its application, Chapter five explains the statistical analysis of collected data, Chapter six introduces the design and building of medical device system and the implementation, Chapter seven describes the results that were obtained from the applying of the method which was discussed in chapter four and their discussion and Chapter eight provides the conclusions and recommendations of the thesis.

CHAPTER TWO

2. THEORETICAL FUNDAMENTALLY

2.1.Medicaldevices:

Medical Devices Defined as “Any instrument, appliance, material, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of… diagnosis, prevention, monitoring, treatment or alleviation of disease“[1].

Medical devices contains instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. and Medical equipment that contains Medical devices requiring calibration, maintenance, repair, user training, and decommissioning – activities usually managed by clinical engineers and any Medical equipment that used for a specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; all of those can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment.
Medical equipment excludes implantable, disposable or single-use medical devices.

Medical devices are articles that are used in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in humans or animals [2].

2.1.1. Classes of Medicaldevices:

General classification of medical devices as four risk based class:

- Class (A) is the low risk level, for example surgical retractors and tongue depressors.

- Class (B) is the low-moderate level, for example hypodermic needle and suction equipment.

- Class (C) is the moderate-high level, for example lung ventilator and orthopaedic implants.

- Class (D) is the high level, for example heart valves and implantable defibrillator [3].

2.1.2.Medical devices maintenance:

Medical devices utilization has been major points of interest for many hospitals due to their direct impact on performance and patient safety. Achieving the highest possible utilization will improve the performance and patient safety. There are many variables that affect the performance of hospital staff and medical devices maintenance schedule is one of them. A simulation method was implemented to improve the maintenance processes of medical devices [4].

Medical devices maintenance is an integral aspect of an efficient health system. Preventive maintenance policies have been studied for decades. These policies consider the timing of two types of maintenances: preventive maintenance and corrective maintenances. Corrective maintenance is more costly and time intensive than preventive maintenance, but only occurs when a machine fails. A good preventive maintenance policy considers the trade-offs between more frequent preventive maintenances and the more expensive corrective maintenances.

The medical industry is becoming quite complex with a huge capital investment being incurred on process automation to enhance the reliability of system. Invariably, the proper maintenance of such systems and the frequency of maintenance are some of the issues that are gaining importance in industry [5].

2.1.3. Networked Medical devices systems:

Issues in emerging medical device Systems may be characterized as those systems that are pushing the envelope of regulated technology. Examples are closed-loop or networked device systems. In today’s health care environment, it is common to have a patient connected to several medical devices simultaneously.

These devices may be delivering drugs, regulating breathing, or reporting a physiological status. Caregivers must aggregate, analyze, and react to this information in a coordinated way. In the operating room, for example, one may find many devices providing life-supporting functions and multiple medical professionals interoperating based on information provided by the various devices (and their own observations). Humans are subject to fatigue, miscommunication, distractions, misinterpretation of information, information overload, and other factors. These factors can combine to contribute to an undesirable patient outcome [6].

The digital technology found in most medical devices today would make it rather easy (at least conceptually) to collect device information, aggregate it, and either present it to a health care provider for some action or use it to trigger an autonomous action by a device. For example, it is routine to simultaneously display data from pulse oximeters, EKGs, and blood pressure devices to monitor patients with cardiac problems; devices delivering radiation treatment to a tumor in an organ that moves can sense organ motion and direct a radiation beam calibrated to the movement. The need to provide health care services in a home care environment, or deliver expert medical practice remotely (telemedicine, emergency response), or perform online clinical lab analysis further underscores the central role of advanced networking and distributed communication of medical information (via electronic health records) in emerging care systems.

Adding computing and control mechanisms to the critical medical information communicated (via networking) establishes a fundamental prerequisite to high-confidence cyber-physical medical systems. This must be done in a way that supports the principled development and implementation of systems of medical systems.

2.1.4. Future Medical devices:

Past, Present, and Emerging Medical Device Systems As in many industries, the technology in medical devices has evolved in tandem with overall technology innovation and the establishment of engineering best practices, transitioning from vacuum tube electronics to transistor-based electronics and from metal to plastics.

Prior to the digital age, medical devices were generally built using analog components in relatively simple designs, with relatively simple user interfaces and limited functionality. The primary method of controlling risk to patients was competent human intervention [7].

Future Medical Devices, High-Confidence Cyber-Physical Systems (CPS) as technological advances and innovation permit medical device systems to decrease in size while increasing in capabilities, it is reasonable to expect that future devices could evolve into ubiquitous supervisory-control, patient-centric systems performing autonomous, cooperative, and coordinated actions, medical devices and systems of the future can be expected to continue the trend towards heterogeneous configurable personalized systems far more capable, and also more complex, than today's. Development Methods As the architecture of medical systems evolves from the domain of macro- and micromechanical systems to nanoscale CPS and biological systems, development methods must fundamentally change. It is likely that a greater dependence on, and trust in, physical and biological models will become necessary.

2.2. Quality management systems:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA), develops and implements national programs to protect the public health in the fields of medical devices and radiological health. These programs are intended to assure the safety, effectiveness, and proper labeling of medical devices, to control unnecessary human exposure to potentially hazardous ionizing and non-ionizing radiation, and to assure the safe, efficacious use of such radiation [8].

2.2.1. Quality control systems:

The quality system regulationis the current Good Manufacturing Practices (GMP) requirements set forth in the Quality System (QS) regulation are promulgated under section 520 of the Food, Drug and Cosmetic (FD&C) Act. They require that domestic or foreign manufacturers have a quality system for the design and production of medical devices intended for commercial distribution in the United States.

The regulation requires that various specifications and controls be established for devices; that devices be designed under a quality system to meet these specifications; that devices be manufactured under a quality system; that finished devices meet these specifications; that devices be correctly installed, checked and serviced; that quality data be analyzed to identify and correct quality problems; and that complaints be processed. Thus, the QS regulation helps assure that medical devices are safe and effective for their intended use. The **FoodandDrugAdministration** (FDA) monitors device problem data and inspects the operations and records of device developers and manufacturers to determine compliance with the GMP requirements in the QS regulation.

The QS regulation is in Part 820 of Title 21 of the Code of Federal Regulations (CFR). This regulation covers quality management and organization, device design, buildings, equipment, purchase and handling of components, production and process controls, packaging and labeling control, device evaluation, distribution, installation, complaint handling, servicing, and records. The preamble describes the public comments received during the development of the QS regulation and describes the FDA Commissioner's resolution of the comments. Thus, the preamble contains valuable insight into the meaning and intent of the QS regulation.

The Quality System (QS) regulation requires that each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured; the quality system should be an integrated effort -- a total systems approach, to satisfy the particular safety and performance needs of a specific manufacturer, product, and user-market. The quality assurance (QA) activities do not simply consist of inspection and testing spot solutions or "fire-fighting," no matter what the product is or how small the manufacturer.

The QS regulation requires that each manufacturer prepare and implement quality system procedures adequate to assure that a formally established and documented quality system is implemented the system should include not only formal documentation, but also an obvious commitment to quality from top management. There should be manifest indications that management recognizes the need for a quality system in order to assure quality products. In many manufacturers, this commitment is accomplished through means such as: a

management policy; assignment of responsibilities and authorities; and general statements and actions such as employee training that define goals of the quality system.

This policy is supported by a number of more detailed quality system documents such as verification methods, sampling procedures, inspection/test procedures, product audits, and records indicating that measurement and monitoring of quality has occurred. The number of documents needed depends on the size and complexity of the operation and the characteristics of the product.

The QS regulation requires the manufacturer to maintain various records such as:

• design history files.

• Device master records.

• Device history records

• Maintenance schedules and records.

• Complaint files and failed device/component files.

• audit reports.

• Distribution records.

• Personnel training records.

In all cases, quality should be considered at the earliest stages in every significant area that has an effect on the quality, safety, and effectiveness of the device. These areas include product development, design verification and validation, component and/or supplier selection, documentation, development of labeling, design transfer, process development and validation, pilot production, routine manufacturing, test/inspection, device history record evaluation, distribution, service or repair, and complaints. Complaints and, of course, favorable comments constitute customer feedback that may result in improvements in the device, labeling, packaging or quality system.

2.2.2. Quality assurance:

Quality assurance is a system which emphasizes that: all employees and suppliers are responsible for their activities; design requirements are established and met; process requirements are established and met; all production activities are controlled; finished product specifications are met; and feedback results in appropriate corrections.

There are several QA systems in common use, including quality control, good manufacturing practices, product design assurance, the ISO 9000 series of international QA standards, and total quality assurance. Quality control is a minimal system which emphasizes test and inspection. The QS regulation is a government mandated QA system for medical device manufacturers. It emphasizes device, labeling, packaging and process design and all aspects of production: facilities, equipment, design development, design and production documentation, correct design transfer, production control, production records and feedback.

Documentation for a quality system is composed of: product-specific technical documentation such as engineering drawings, component purchase specifications, procedures for manufacturing processes and testing; labels, etc.; and general quality system documentation, such as standard operating procedures (SOP's) for employee training, audits, etc., that are applicable for all products. All activities and product quality are monitored; and any deviations from device and process specifications and company policies are fed back into the system where the deviations are corrected. Likewise, complaint and service information are processed and fed back for appropriate corrections. If the required activities including the feedback are performed, the quality system is self-correcting and, thus, the manufacturer is operating in a state-of-control. FDA requires manufacturers of medical devices to operate in a state-of-control.

2.3.Medical devices management software:

Software is fast becoming the differentiator for manufacturers of medical devices. The rewards of software innovation are balanced by the risks and challenges of regulation, stringent quality requirements, market pressures, and

significant complexity. Balancing these competing interests requires tailored application lifecycle management tools that address the unique needs of medical devices companies.

Software can serve as a source of innovation and a key differentiator for medical devices, especially given the adaptability of software and the speed at which software changes can be prototyped and implemented. Software is also becoming more voluminous and complex, which creates significant risk.

Medical Devices Defined "Any instrument, appliance, material…, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of… diagnosis, prevention, monitoring, treatment or alleviation of disease".

Software used as a component of a medical device, Software that is a medical device, Software used in the production of a device, Software used to manufacture a device and Software used in the implementation of the quality system.

2.3.1. Software challenges in the medical device industry:

- Management of Documentation and Records.
- Identification and Traceability.
- Document Controls and Change Management.
- Managing Risk and Reducing Recalls device and Software Quality.
- Growing Volume of Software and Product Variants puts Quality at Risk.
- Cost and Consequences of Recalls.

2.3.2. Growing volume of Software:

Growing volume of Software and product variants puts Quality at risk, should be dealing with the complexity of software products and product lines by Reuse capabilities and traceability provide greater understanding of complex software products and the dependencies or impact of change across the product line, leading to better quality and less rework/error.

2.4. Medicaldesign management programs:

Medical design control is an application of technology to health care in hospitals. It can be a part of the health care system involves the interface of instruments with computer systems to health care team.

2.4.1. Quality system requirements concerning design control, FDA's quality system regulation:

- Design and developing planning.
- Design I/P & O/p.
- Design review.
- Design verification & validation.
- Design changes, transfer and history files.

2.4.2. Medical Equipment Management:

Medical Equipment Management Program (MEMP) is established in hospitals to provide safe and reliable operation of medical equipment and promote its effective utilization. This program defines procedures and policies to manage activities related to medical equipment, from their selection and acquisition to decommission. MEMP ensures that devices can provide reliable and accurate information to clinicians, operate safely for patients, and are used to their fullest capacity.

The life cycle of medical devices should be thoroughly considered for effective management. Deficiencies in managing each stage of the life cycle, especially in the earlier phases can cause more problems in the succeeding stages. For example, if the maintenance capabilities are considered during acquisition stage, it can hinder the challenges that might be faced during the maintenance stage of the equipment [9].

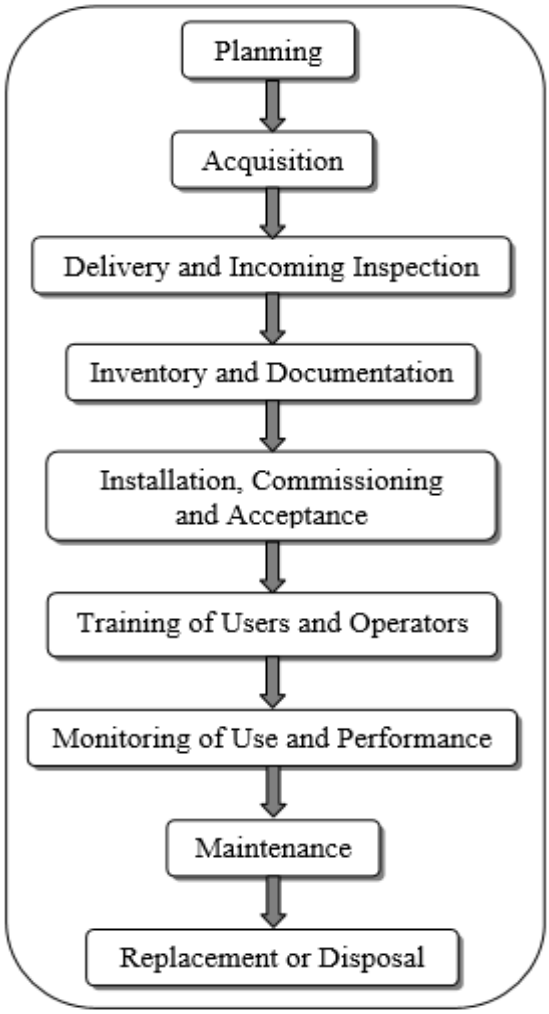


Figure (2.1): Life Cycle of Medical Equipment

The intrinsic quality, safety, and effectiveness of a device are established during the design phase. Statistics show that a large number of medical-device recalls are a result of inadequate design controls. Design input is the starting point for product design. A frequent complaint of developers is that "there's never time to do it right, but there's always time to do it over." The consequence of a recall should not be limited to the end-user, because it can result in losses for the manufacturer. Therefore, it is in everyone's interest to "do it right the first time." Good design controls lay the foundation for the healthy design and development of medical devices in general.

Properly instituted, a robust design control process can provide the manufacturer with the opportunity to address and/or correct problems early in the process [10].

CHAPTER THREE

3. BACK GROUND STUDIES

L. Contreras, et aL, Modi, and C. Pennathur (2002) studying the historical roots of simulation for the practice of skills, problem solving, and judgment are evident. Medical simulation in primitive forms has also been practiced for centuries; Physical models of anatomy and disease were constructed long before the advent of modern plastic or computers.

About preventive maintenance, a study at a distribution warehouse has been presented for a conveyor system. The integrating predictive maintenance strategies with production planning strategies have been used to reduce of downtime for the management of device breakdown and failure conditions by simulation with Arena. For instance, the downtime was reduced more than 50 % and work in process inventory was reduced more than 65 % [11].

Duffuaa et al,Arya et al,Prasertrungruang and Hadikusumo (2003) have devised a conceptual model for repair and maintenance systems which is based upon the concept of simulation and facilitates operations of the repair and maintenance systems, in identifying the probability distribution of the repair time concluded that the average timing failure, average outage duration, and average annual downtime are the basic indices whose distribution function is exponential. This leads to justification for assuming constant failure rates and repair rates for each distributor segment. In effect, they suggest analytical methods for a reliable evaluation of a distribution network.

Since repair time is much larger than failure times, approximate relations are expensed for obtaining reliability indices of series parallel systems. Average reliability indices are evaluated via analytical techniques, whereas simulation techniques are employed to generate the distribution of these indices, they have also introduced a model for identifying significant factors affecting the repair time by exerting the simulation [12].

Mohammed Rawashdeh, ; Adnan Al-Bashir and Wassem AlHawari (2006) design successful implementation of any simulation project, it is particularly important to have a right approach to the requirement collection and the experimentation phases. This paper intends to provide an integrated framework for those two phases in a simulation project, the simulation was used modeling to study the maintenance activity of QAMH and establish alternative scenarios to enhance the efficiency of the MDMS.

Girginer, N. Sabin (2007) research has been presented for staff planning with alternative structures of simulation models and performance measures. In maintenance engineering, a simulation model has been developed by using Arena for MDMS to improve medical devices reliability and availability [13].

A team work shop identify research at (2009)as Networking and Information Technology Research and Development (NITRD) Program, one of the few formal interagency R&D activities within the Federal government, comprises the Government's main unclassified R&D investments in advanced networking, computing, software, and related information technology (IT). The NITRD Program also supports research in the socioeconomic implications of IT and in development of a highly skilled IT workforce.

In this research NITRD's HCSS PCA supports R&D in scientific foundations and innovative and enabling software and hardware technologies for the design, control, assurance, verification and validation, and certification of complex, networked, distributed computing systems and cyber-physical (IT-enabled) systems such as aircraft and power grids. To be capable of providing advanced services, these systems, including their software, must be reliable, predictable, adaptable, scalable, robust, safe, secure, stable, and in many cases, certifiably dependable. The goal of HCSS R&D is to provide a sound and practical technology base for deeply and fully integrating embedded computation and physical dynamics, networked communications, and control in a unified, coordinated, and continuous manner to routinely build high-confidence, optimally performing computing systems that interact properly with humans and the physical world in changing environments and unforeseen conditions. These systems, often components of larger physical and IT systems, are essential for effectively operating life-, safety-, security-, and mission-critical applications.

Kaufman and Lewis (2011) examine single machine systems where process time may increase as the machine deteriorates. The machine deteriorates one state at a time in random time intervals. Two models are evaluated: repair and replacement. The repair model has random repair times with a positive mean. The replacement model has an instantaneous repair time. It is shown that the optimal policy is monotone in the machine state.

Burgunda V. Sweet, PharmD, FASHP; Ann K. Schwemm, PharmD, MPH; and Dawn M. Parsons (2011) At study that discuss the classification of a product as a drug or medical device can have an impact on clinicians and payer, Some products regulated by the FDA do not fit exclusively into the category of drug or device but are instead a combination of 2 or more single-entity products (e.g., drug, biological, and device). A wide variety of combination products exist, but they generally fall into one of a few categories: those that are physically, chemically, or otherwise combined and produced as a single entity [14].

David Arney, Krishna K. Venkatasubramanian, Oleg Sokolsky and Insup Lee (2011) this paper focused on the challenges involved in securing networked medical devices. And provide an overview of a generic networked medical device system model, a comprehensive attack and adversary model, and describe some of the challenges present in building security solutions to manage the attacks.

Shane S. Clark and Kevin Fu (2011) scientific research presents three major considerations that must be addressed by researchers working on security and privacy for IMDs and outlines two challenges from the computer science community. Our hope is that future research can leverage the strengths of both the computer science and biomedical communities to produce new and e□ective approaches to IMD security and privacy [15].

Villars-sous and Yens (2011) In this technical research have been developed specifically to aid a health facility or a national ministry of health to establish or improve a medical equipment maintenance programed. Its address medical equipment inventory management, maintenance, and computerized maintenance management systems [16].

A. Al-Bashir, M. Rawashdeh, R. Fouad and H. Aisheh (2012) they working on study to Improvement of Process and Staff Utilization in medical devices maintenance system by using simulation, The simulation studies for the staff planning and measurement of service efficiency have presented in production systems, health service systems, shopping centers, education and finance facilities, traffic systems etc. in service systems.

Gregory Daniel, Heather Colvin, Saha Khaterzai, mark McClellan and Pranav Aurora (2015), This work explain the important of Medical devices and show how it play a critical role in health care, Access to reliable and meaningful information about the safety, effectiveness, and quality of devices is essential to inform care and improve patient outcomes. This report represents the Planning Board's long-term vision for a National Medical Device Post market Surveillance System (MDS) and recommended strategies for implementation [17].

The background studies are useful for Finding background information at the beginning of the research that can provide Broad overview of the medical equipment managing programs, Definitions of the terms, present Introduction to key issues, identifying Names of people who are authorities in the control program field,determines Major dates and events in same researches, finding the Keywords and subject-specific vocabulary terms that can be used for database searches and works.

CHAPTER FOUR

4. METHODOLOGY

4.1 Overview of Methodology:

This chapter provides an obvious illustration of the methods that were applied in this study. The technique of the proposed system of this research can be summarized in steps. The first step collects data that needs to design the program and implement it, the second step builds control program for medical devices and in the third step implements the data of devices to the system, finally the applied program using to facilitate the flow of work in alrawda hospital.

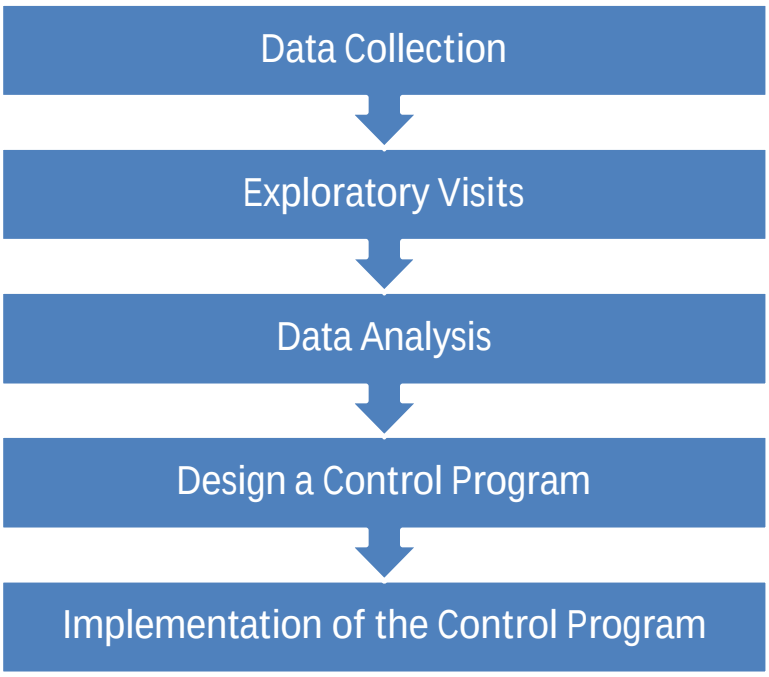


Figure (4.1): flow chart for steps of methodology.

4.2. Data collection:

Data collection is a type of data that has been published in text books, references and websites, called secondary data that is available in these sources about research

area to increasing the levels of research validity and reliability, which can be the first step.

4.3. Exploratory Visits:

Second step is visits,its primary data collection; that can be divided into two groups quantitative and qualitative.

4.3.1. Quantitative data collection:

Is based on mathematical calculations in various formats, include questionnaires with closed- ended questions that will gathered from different hospitals.

4.3.2. Qualitative data collection:

Qualitative do not involve numbers or mathematical calculations, is closely associated with words, sounds, feeling, emotions, colors and other element s that are non-quantifiable. Qualitative data collections include interviews with medical staff to collect information that support the aims and objectives of research for designing control program for medical devices.

4.4. Data analysis:

The purpose of analysing data is to obtain usable and useful information, the analysis describe and summarize the data, identify relationships and difference between variables and compare it.

In first step may take useful information from resources and in second step take a small sample normally associated with qualitative data to determine people's attitudes to a particular phenomenon, Third step is applied statistical techniques to a quantitative data by using SPSS program.

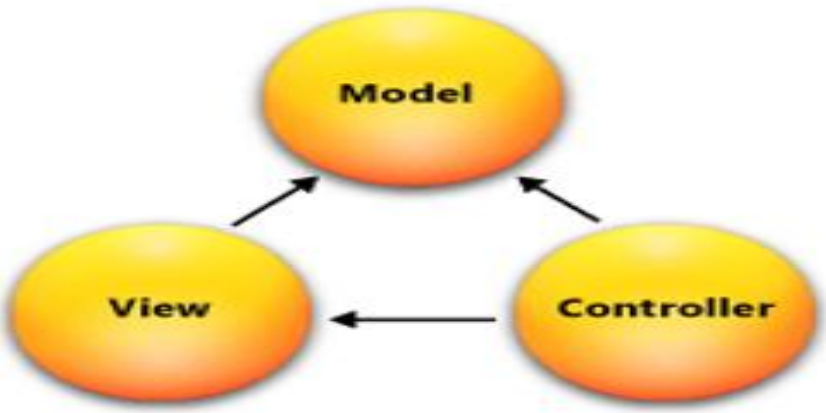
4.5. Building program:

The study will design a program to control equipment's in hospital, with the needed parameters; the health care team in the hospital will participate during the study period (interviews, questioner). The applied data will be collected from specific hospital (analysis) following steps:

- Define the problem.
- Developing a Simple Program (Create a simple program using specific software, Use the tools to facilitate development of programs).

- Adding Files to a program (Use basic data that concern to medical devices to control the data).
- Reviewing the details of Source.
- Building and Running the Program.
- Changing Program Options and Fixing Errors.
- Building the interface Window.
- Using the Watch Window with Structures.
- Adding control roles.
- Displaying Graphs.
- Animating the Program and Graphs.
- Adjusting the Gain.

The study will apply the basic of design by using ASP.NET MVC software - is a web application framework developed by Microsoft, which implements the model–view–controller (MVC) pattern. It is open-source software, apart from the ASP.NET Web Forms component which is proprietary.



Fig(4.2):Model-View-Controller (MVC).

4.6. Implementation of program:

Once the control program has been established, it can be a very helpful tool within the clinical engineering department and the health-care facility as a whole.

It is imperative for any organization intending to run an effective medical equipment management program to have and maintain an equipment inventory.

Implementation of the program is the practical part of this study is constructed to experiment on how to implement an effective control program and how to test and validate it sufficiently. Such a software component must be capable of reading,

updating and extracting information. The resulting software component needs to be integrated within the whole existing system. After implement the program it should be recording the equipment information to determine what items are to be collected and to operate the computer system.

The records are a working document that is regularly checked and updated to accurately reflect the status. When used appropriately, the program serve as an important and powerful tool to improve management of many key aspects of health-care.

CHAPTER FIVE

5. ANALYSIS OF QUESTIONNAIRE

5.1. Questionnaire field applied:

This chapter address the analysis and data on a sample questionnaire distributed community's (48) of workers usingStatistical Package for the Social Sciences (SPSS) program.

The questionnaire constructed from ten questions about control programming and the progress of health care by using software in management, the questionnaire is solved in four hospitals (alrawda, alzaytona, alsoudi and ystabsheron) and analyzed by SPSS program, the form of the questionnaire is illustrate at the appendixes in appendix (A).

5.2. Types of Questionnaire:

A questionnaire consists of a number of questions that the respondent has to answer in a set format. A distinction is made between open-ended and closed-ended questions. An open-ended question asks the respondent to formulate his own answer, whereas a closed-ended question has the respondent pick an answer from a given number of options. The response options for a closed-ended question should be exhaustive and mutually exclusive.

Four types of response scales for closed-ended questions are distinguished:

- Dichotomous, where the respondent has two options.
- Nominal-polytomous, where the respondent has more than two unordered options.
- Ordinal-polytomous, where the respondent has more than two ordered options.
- (Bounded)Continuous, where the respondent is presented with a continuous scale.

5.3. Statistical analysis for the data:

Using (SPSS) program to analysis as follows clarify the following:

Table(5.1): Existence of data base documentation for devices

	Frequencies	Percent
Yes	15	31.3
No	33	68.7
Total	48	100

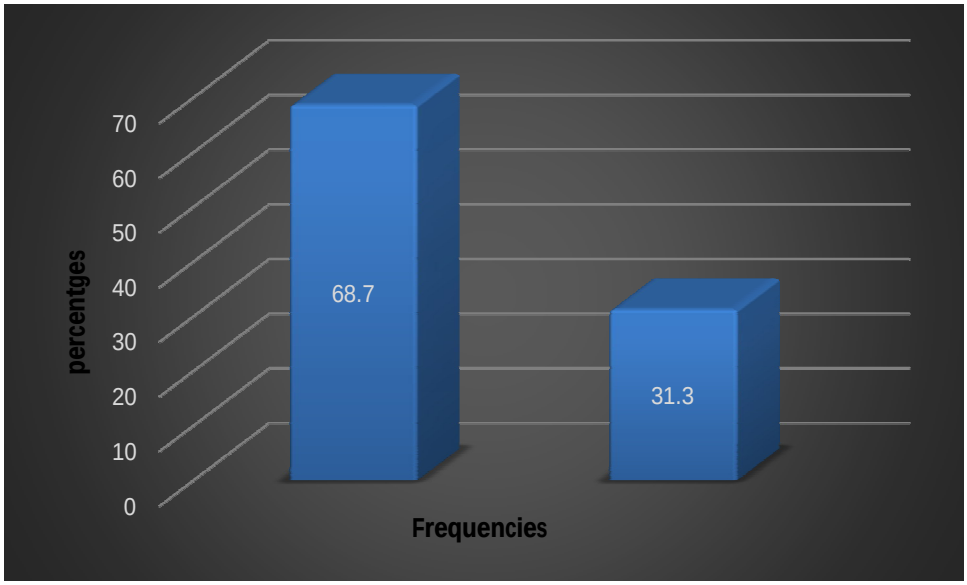
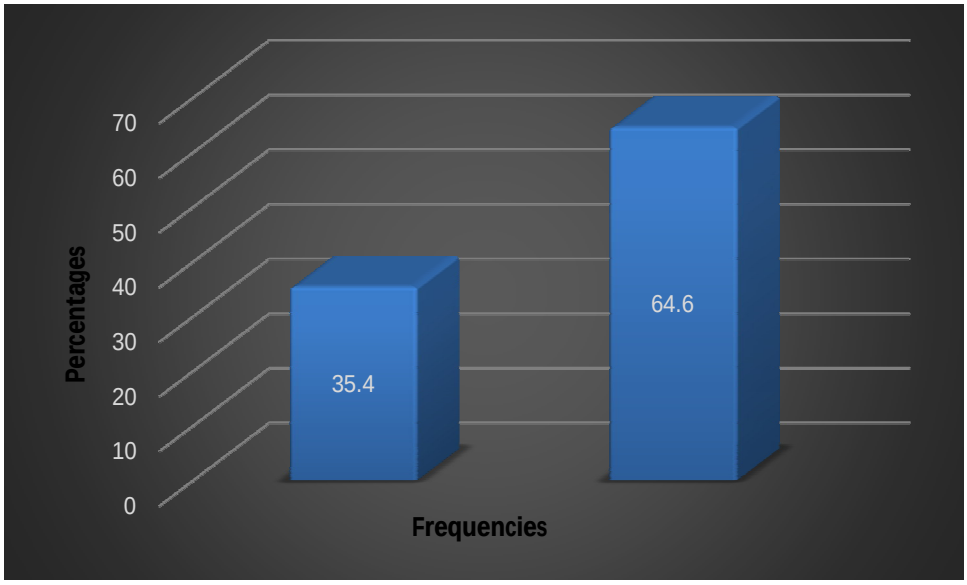


Figure (5.1):the Frequencies and percentages of data base documentation in hospitals.

Table (5.1) shows the frequency distribution of the samples for question one, that found the most hospitals have not database documentation for medical devices, And figure(5.1) illustrate the Frequencies and percentages for the samples such as found that 68.7% have no data base documentation and 31.3% they have of the sample size.

Table(5.2): control program facilitate the flow of work.

	Frequencies	Percent
Agree	31	64.6
Disagree	17	35.4
Total	48	100

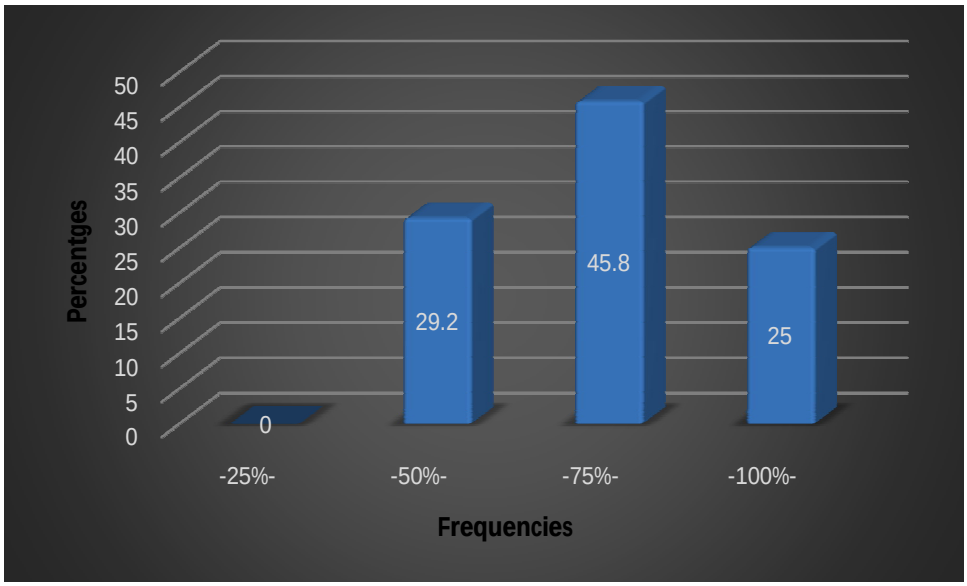


Figure(5.2): the percentages for designing control program as the vision of workers in hospitals.

Table (5.2) shows that large number of the samples supports the need of design a program to be a single centralized location for all data concerned to medical devices, that can facilitate the flow of work and provide high accuracy control managing and risks, and figure (5.2) illustrate the Frequencies and percentages as wit found that 64.6% Agree and 35.4% disagree of the sample size.

Table (5.3): control program controlling the maintenance for devices.

	Frequencies	Percent
25%	0	0
50%	14	29.2
75%	22	45.8
100%	12	25
Total	48	100



Figure(5.3): illustrate that Frequencies and percentages for words such as it found that 29.2% 50% and 45.8% 75% of the sample size.

In table (5.3) found about have of sample size think designing of control program can control preventive and maintenance for devices, and Figure (5.3) illustrate that Frequencies and percentages found that 29.2% 50% and 45.8% 75% of the sample size.

Table(5.4):system development provide cost control.

	Frequencies	Percent
Agree	44	91.7
Disagree	4	8.3
Total	48	100

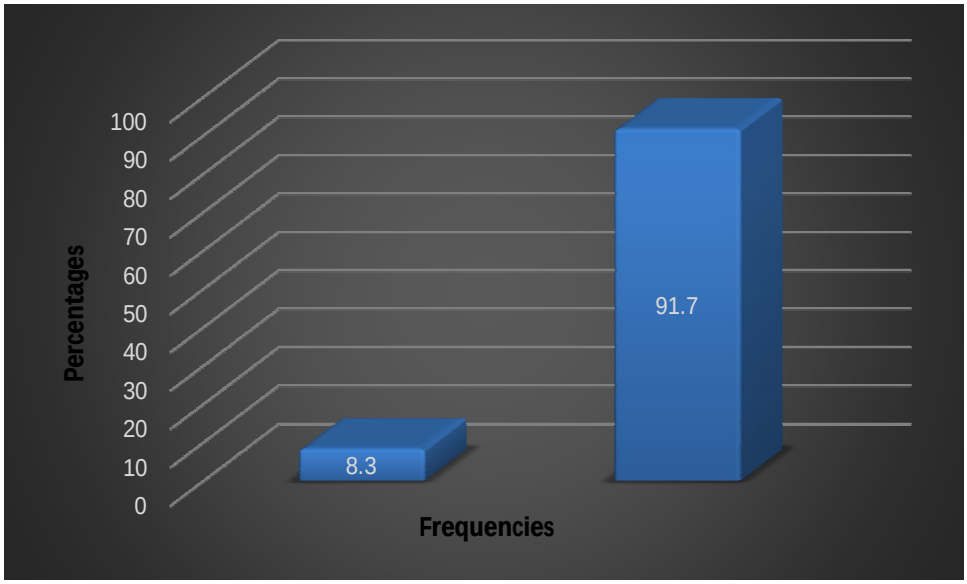


Figure (5.4): illustrate the Frequencies and percentages for words such as it found that 91.7% Agree and 8.3% disagree of the sample size.

Table (5.4) shows the frequency distribution of samples supports the system development of computerized applications in hospital provide cost control, and figure (5.4) illustrate that 91.7% Agree and 8.3% disagree of the sample size.

Table(5.5): hospital procedures to get new device.

	Frequencies	Percent
Yes	33	68.8
No	15	31.2
Total	48	100

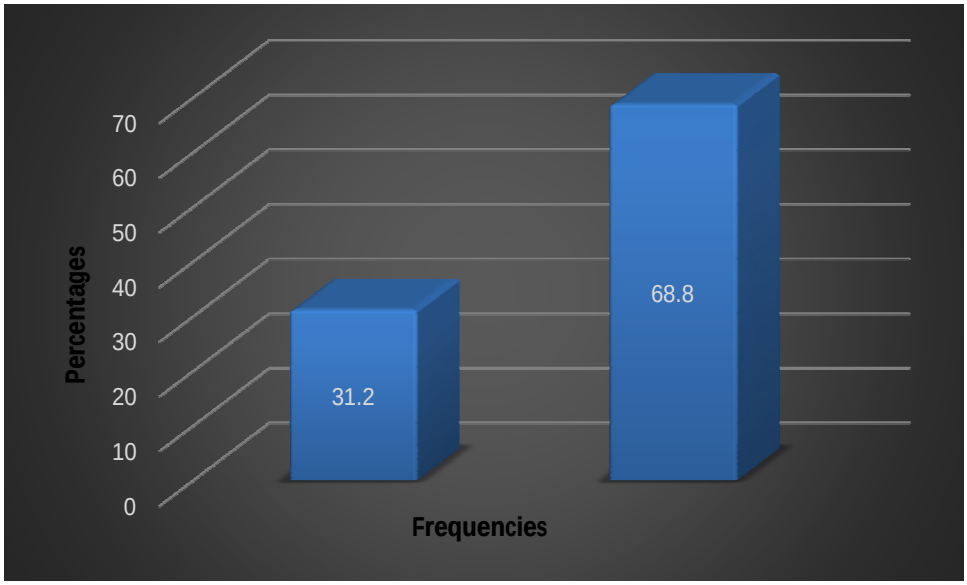


Figure (5.5): illustrate the Frequencies and percentages for words such as found that 68.8% Yes and 31.2% NO of the sample size.

Table (5.5) shows the frequency distribution of the sample that explain the hospital procedures are developing in getting new devices and figure (5.5) illustrate 68.8% agree.

Table(5.6): computer program control is help medical staff to support health care.

	Frequencies	Percent
Rarely	18	37.5
Sometime	20	41.6
often	10	20.9
Total	48	100

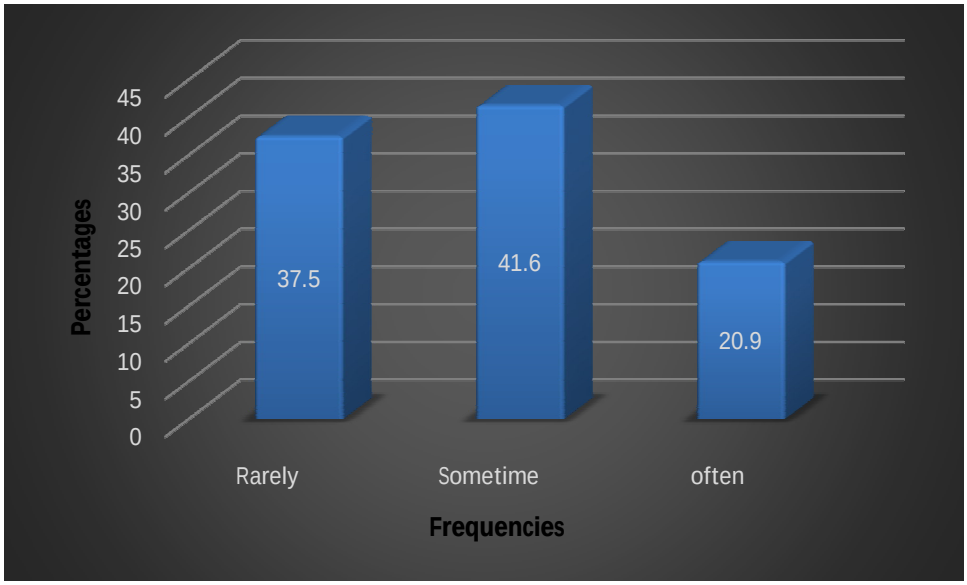


Figure (5.6): illustrate the Frequencies and percentages for words such as it found that 37.5% rarely and 41.6% sometime and 20.9% often of the sample size.

Table (5.6) shows the frequency distribution of the samples, most of them agree that the computer program control help the medical staff to support health care and figure (5.6) shows 41.6% think it helps some times.

Table (5.7):importance of schedules processing managed the workloads.

	Frequencies	Percent
A lot	10	20.8
A little	38	79.2
Total	48	100

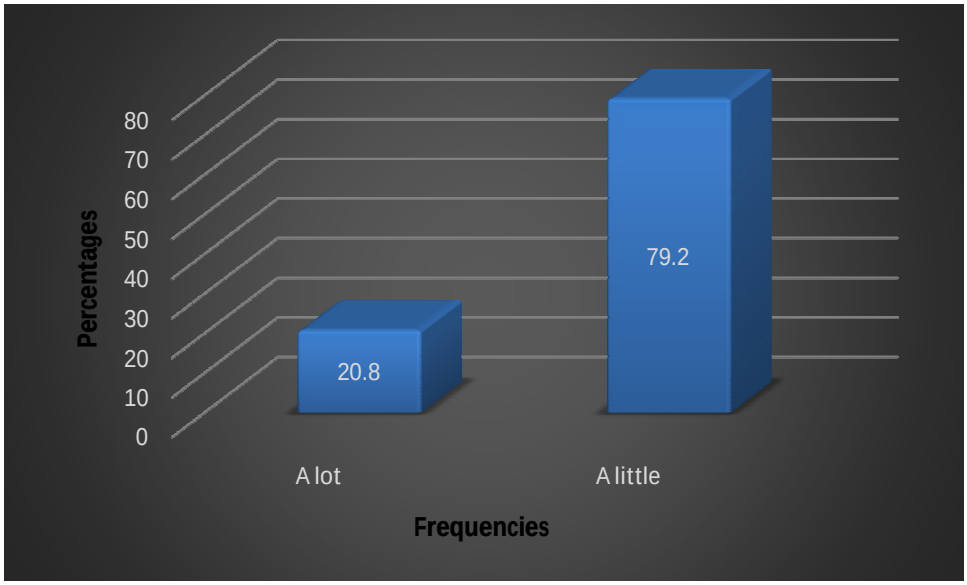


Figure (5.7): illustrate the Frequencies and percentages for words that 20.8% thoughts a lot and 79.2% a little of the sample size.

Table (5.7) shows the frequency distribution of the samples support that workloads properly managed by using medical devices and their accessory so it needs schedules processing to ensure that all jobs are processed and that deadlines and priorities are considered and figure (5.7) illustrate 79.2% disagree with that point.

Table (5.8):necessity oflimitation to access database source and software.

	Frequencies	Percent
Yes	12	25
No	36	75
Total	48	100

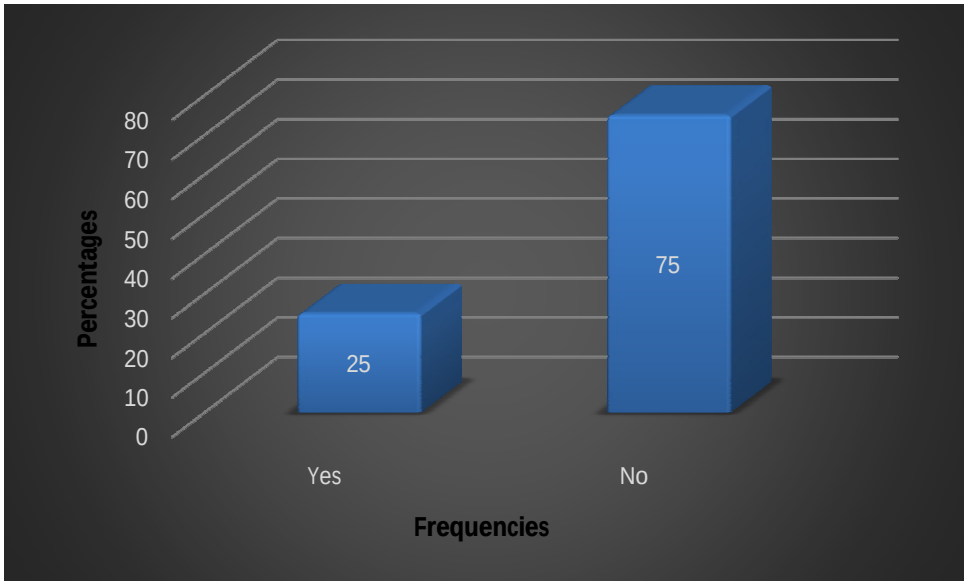


Figure (5.8): illustrate the Frequencies and percentages for samples that 25% Yes and 75% No of the sample size.

Table (5.8) shows the frequency distribution of the samples explain the necessity of making procedures for limiting access to the database source and operating software, causethe program containmedical tools , devices and equipment's information, and figure (5.8) illustrate that 75% disagree with limitation.

Table (5.9): existence of complaints with legal requirement of design QS in past year.

	Frequencies	Percent
Yes	16	33.3
No	32	66.7
Total	48	100

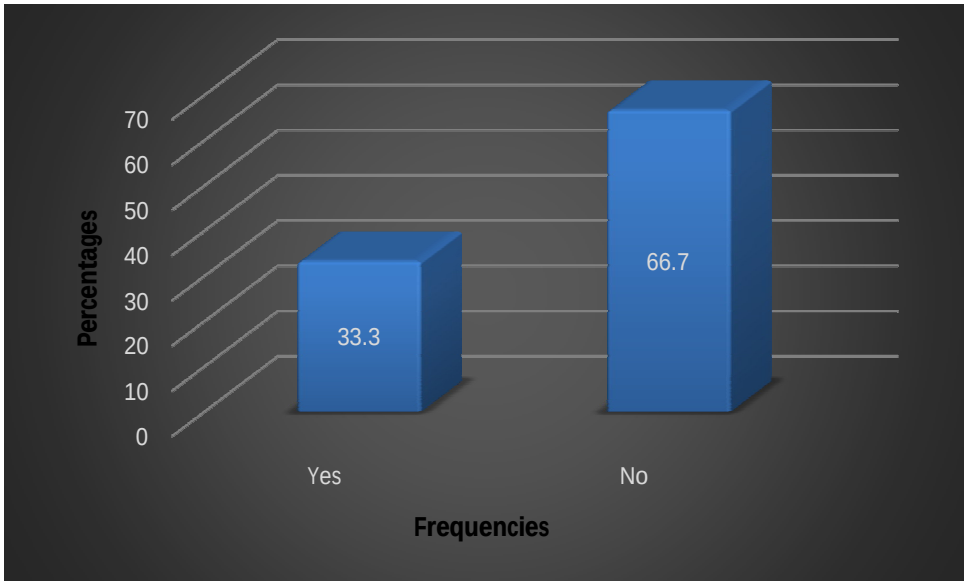


Figure (5.9): illustrate the Frequencies and percentages that 33.3% thought it foundand 66.7% thoughts it isn't the sample size.

Table (5.9) shows the frequency distribution of the samples have there been any complaints or allegations of non – compliance with professional standards, regulatory and legal requirements of the design control of quality systems in the past year in our country and figure (5.9) illustrate that 33.3% agree.

Table (5.10):management provides guidance for complete procedures in hospital.

	Frequencies	Percent
Strongly agree	10	20.8
Agree	15	31.2
Strongly disagree	23	48
disagree	0	0
Total	48	100

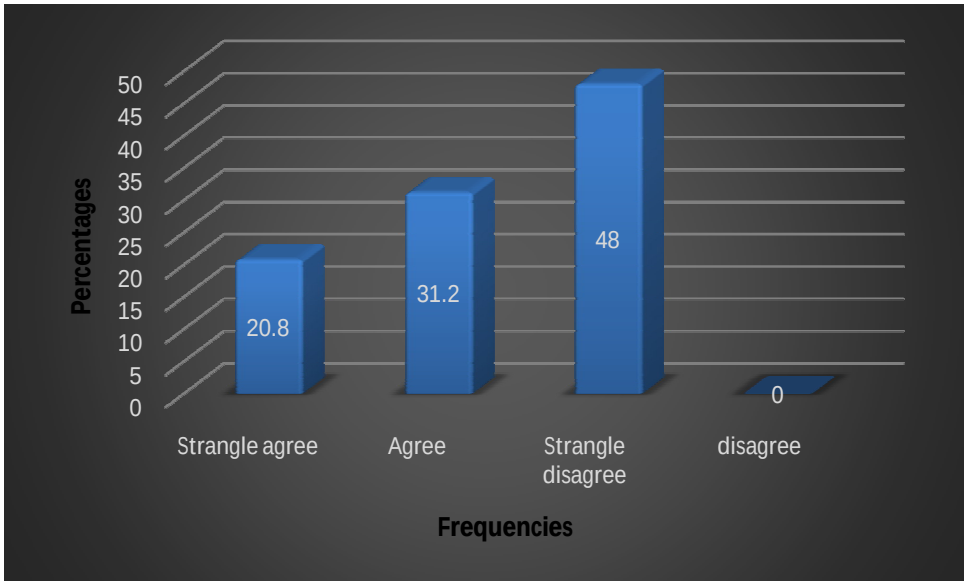


Figure (5.10): illustrate the Frequencies and percentages for words such as found that 20.8% strongly agree and 31.2% Agree and 48% strongly disagree of the sample size

Table (5.10) shows the frequency distribution of the sample if there have been any complaints or allegations of non – compliance with professional standards, regulatory and legal requirements of the design control of quality systems in the past year in our country and the chart in figure (5.10) illustrate the strongly disagree of workers at sample size.

The questionnaire confirms the importance of implementcontrol programto progress of health care by using software in management.

CHAPTER SIX

6. DESIGN AND IMPLEMENTATION

6.1. Building program:

- structured for the whole program:

The main units to building (control program) clarify in block diagram that explainbuilding medical devices system:

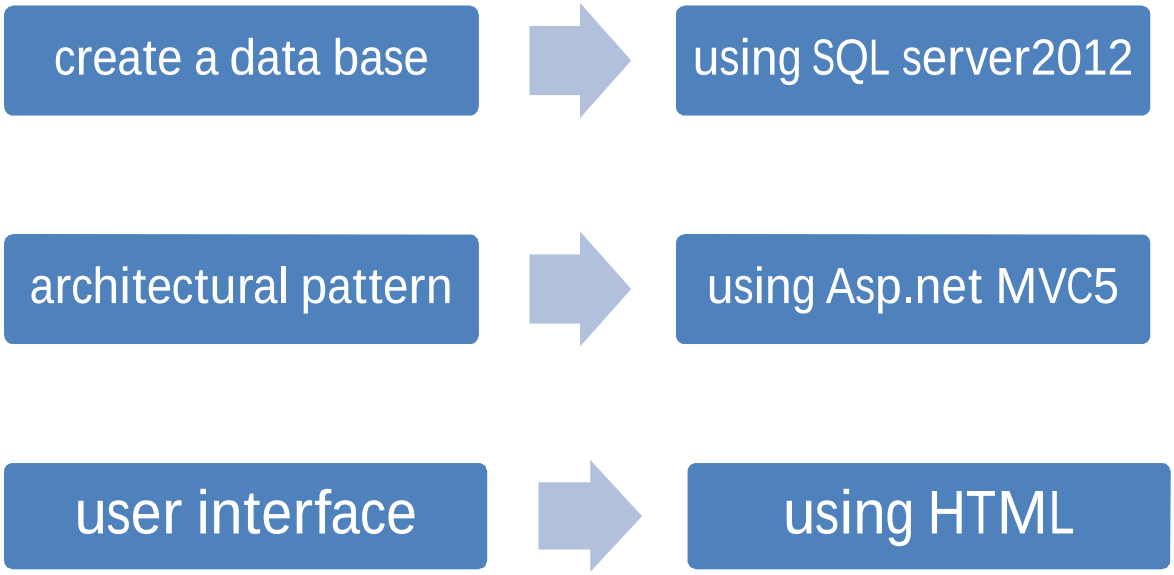


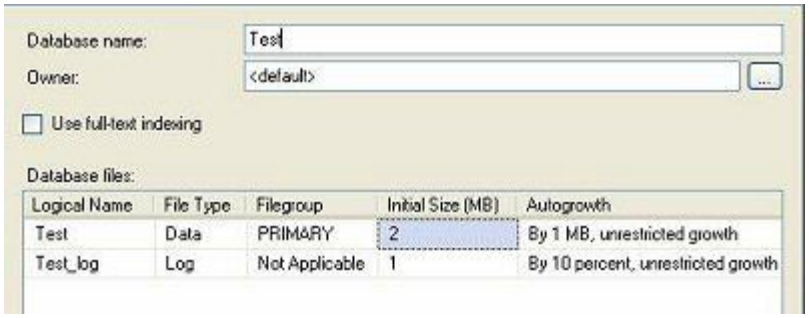
Figure (6.1): units of building control program.

6.1.1. Create a database:

Creation of database using SQL server 2012, A “Database” in SQL Server is a container that holds a group of related objects. In addition to storing the actual

data, a Database also stores the structure of how that data is saved (called a Table), and any related helper objects such a Queries (saved ways to look data up).

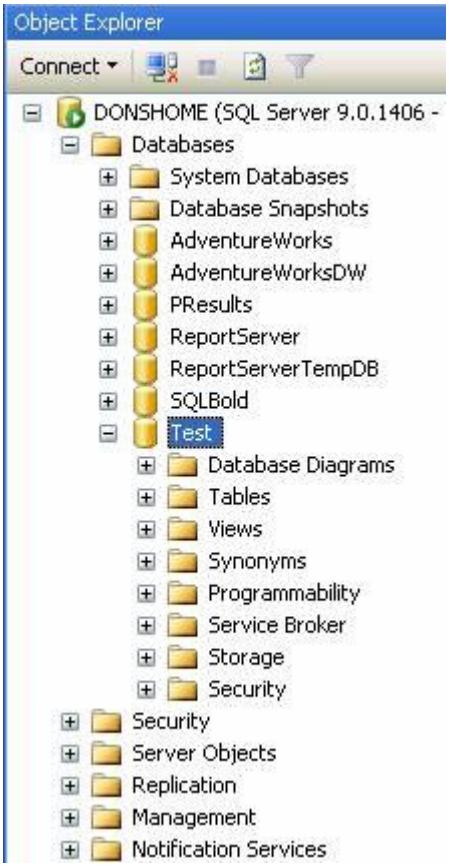
To begin, create a Database using the graphical interface called the “SQL Server Management Studio”, From the Windows Start Menu, select “Microsoft SQL Server”, and then “SQL Server Management Studio”. Once the Management Studio starts, right click the Databases folder and select new Database. Enter a name in the “Database name” text box as in figure (6.2).



Figure(6.2): create a database.

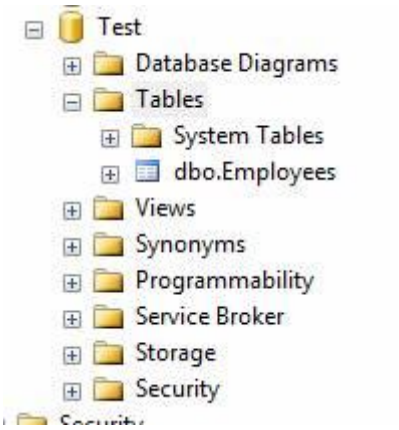
As the writer type the database name in, the Logical Name for the file types Data and Log will automatically fill in as well. The “Data” file is where the actual data is saved on the hard drive. The “Log” file keeps track of any changes to that data, and then click‘OK’.

Now that the database is created, a structure to hold the actual data is needed. This structure is called a Table. Think of Tables as containing columns and rows, like a spreadsheet, to create a Table, expand the Databases folder, and then expand the newly created database, Right click “Tables” and select “New Table”. The user will be prompted to fill in “Column Name” and “Data Type”, and in the next row, enter a Column Name with a data type and so on, Save the Table by clicking the Save icon from the top menu bar, It will prompt for table name, enter “Employees” and click OK.



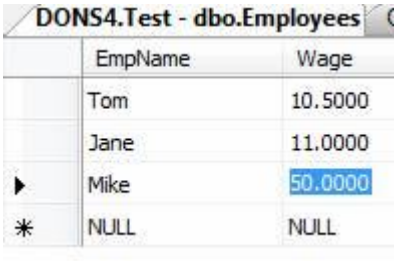
Figure(6.3): create a table.

After saving the table expands the table's folder from the left menu to enter data into the newly created Employees table, as shown in figure (6.4).



Figure(6.4): enter data into the newly created table.

The newly created Employees table will be listed. Right click it and select “Open Table”. A small grid will open. Enter a few data lines as shown in figure (6.5). Moving to a new line after entering data automatically saves.



Figure(6.5): enter data into the newly created table.

After this step using in the SQL Server Management Studio, created a Database, a Table, and entered data.

6.1.2. Architectural pattern using ASP.NET MVC5 software:

The study will apply the basic of design by using ASP.NET MVC software -is a web application framework developed by Microsoft, which implements the model–view–controller (MVC) pattern. It is open-source software, apart from the ASP.NET Web Forms component which is proprietary.

-ASP .NET MVC Framework Components:

Model is represent application data and behavior in terms of its problem domain and independent of UL, Model contains of Business/domain logic, Model objects and retrieves and store model state in a persistent storage (database).

Views, view is represent the HTML markup that we display to the user, its component is Display application’s UI and UI created from the model data.

Controller which is responsible for handling an HTTP requests, consist of Handle user input and interaction, Work with model and Select a view for rendering UI.

Steps to build the program:

- Create Database, Create Table.
- Preparing a Model.
- Add a controller.
- Add a View.

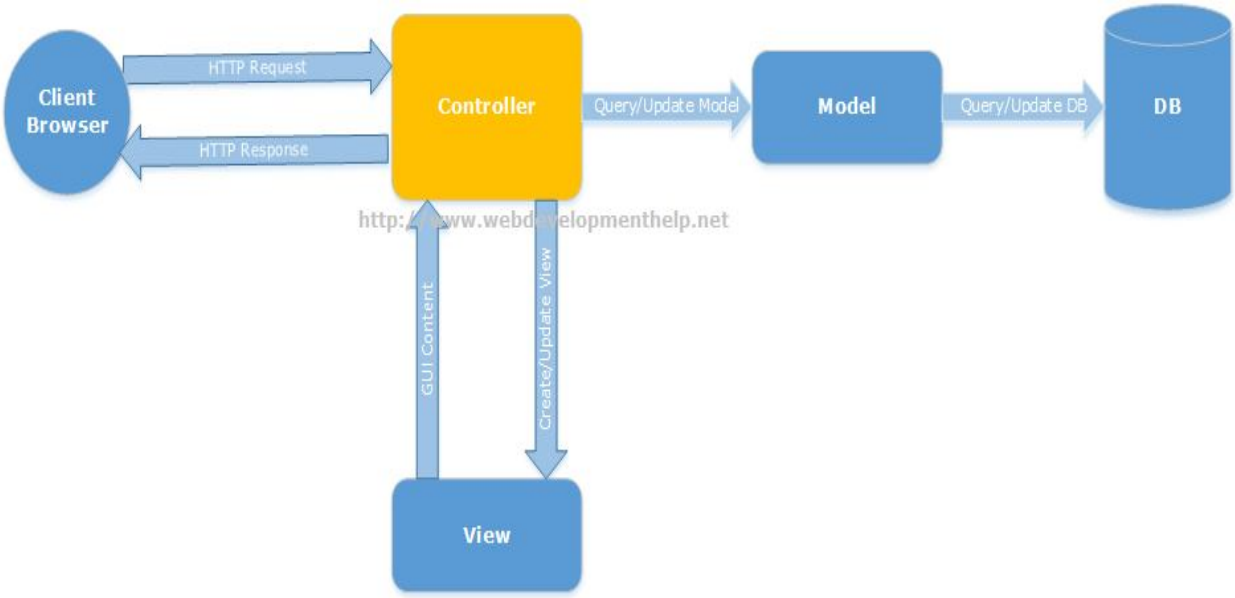


Figure (6.6): steps of building control program using ASP.NET MVC5.

1. Creating MVC5 project in Visual Studio 2013:

- Open Visual Studio Express 2013 for Web and create "New Project" as "File –> New Project.
- Choose "ASP.NET Web Application" template as shown in figure (6.7). Name the project as "Medical equipment", choose location and press "OK" button.

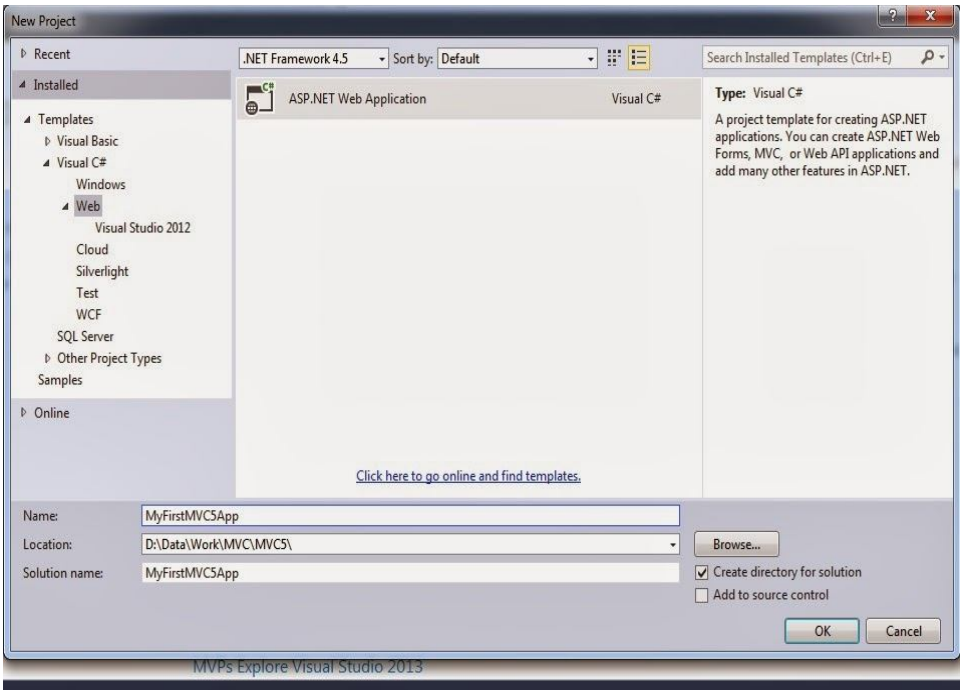


Figure (6.7): create new project.

- In next dialog, choose “MVC” as template and again press “OK” button.

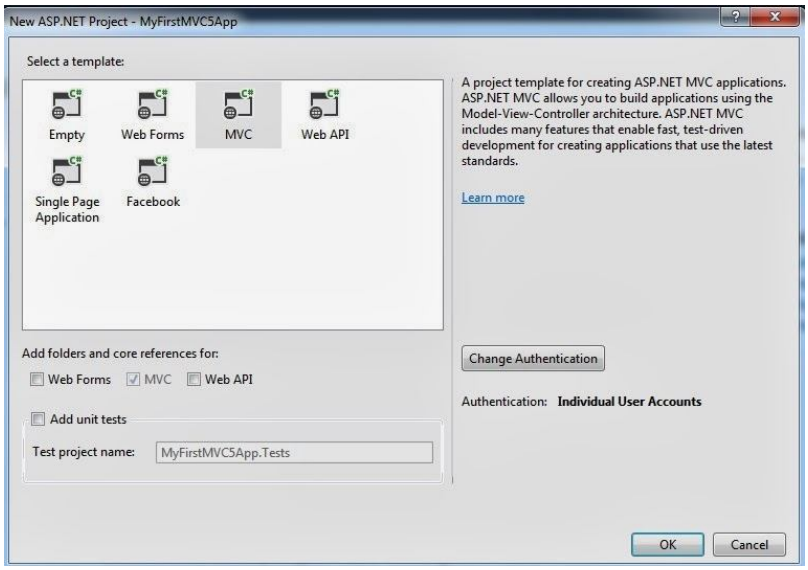


Figure (6.8): choose MVC.

- A new ASP.NET MVC 5 project will be created as follows in figure (6.9) that can easily find the “Controllers”, “Models” and “Views” folder in solution explorer.

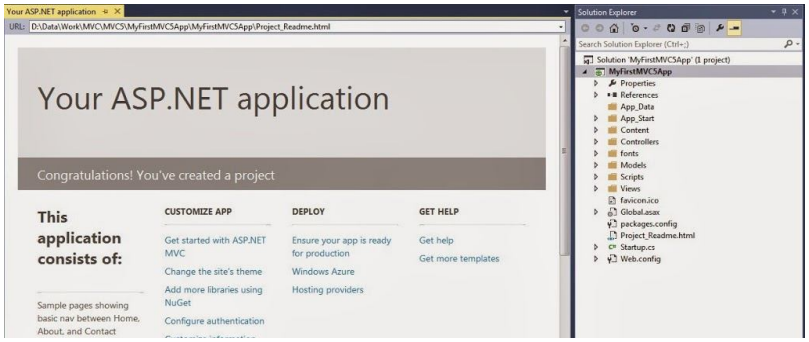


Figure (6.9): create MVC.

2. Preparing a Model:

- In order to prepare a model, right click on “Models” folder and choose “Add”, then “Class”.
- Name the class as “devices”.

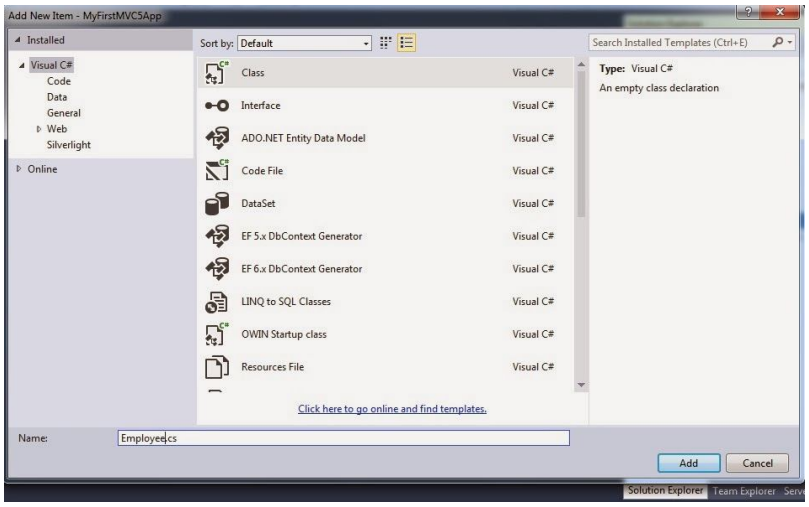


Figure (6.10): prepare amodel.

- As discussed earlier that “Model” is the representation of data structure in our Data Source, so it can assume this “devices” class represents an

Employee table in our database with columns as “classification of device”, “type of device” and so on.

The code of preparing the modelillustrate at appendixes of the project in appendix (B, a), the programmer can change the details according to requirements of the project.

3. Add a Controller:

- To add a controller to the project, right click on “Controllers” folder, choose “Add”, then “Controller”.
- From “Add Scaffold” dialog, choose “MVC 5 Controller – Empty” and press “Add” button as shown at figure (6.11):

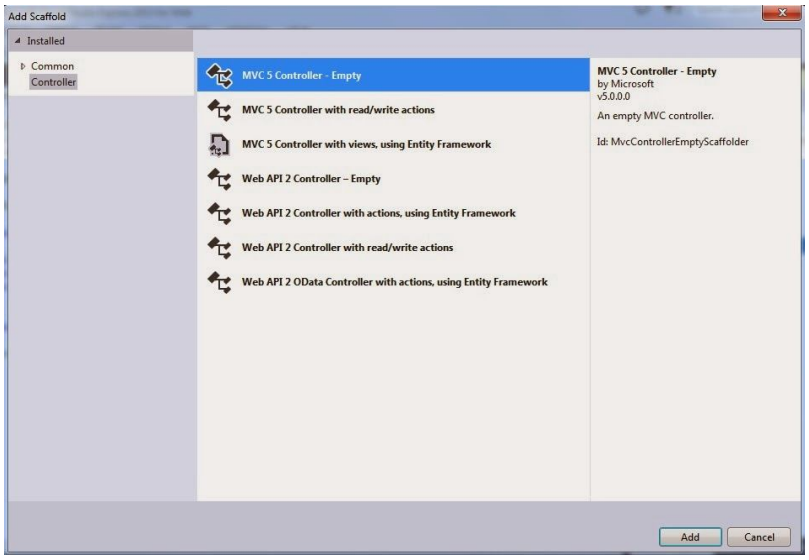


Figure (6.11): choose controllers button.

- Name the controller as “equipment Controller” in next dialog and press “Add”. A new controller will be added to “Controllers” folder. Controller code generated will be as in figure (6.12):

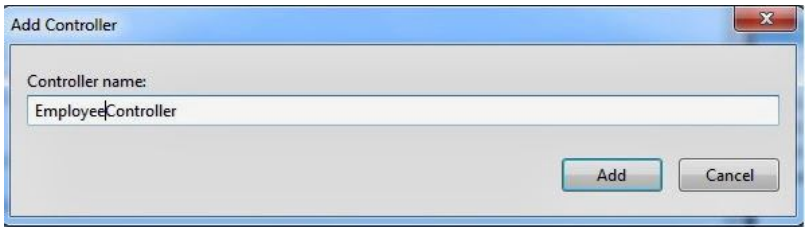


Figure (6.12): add controller.

Thecode of adding the controller illustrates at appendixes of the project in appendix (B, b), the programmer can change the details according to requirements of the project, and a few important things explain that:

- EmployeeController inheriting from base Controller class has a method named Index(). This Index() method will be the default method called when accessing this controller.
- In order to generate HTML response, above Index() method uses a view template i.e. represented in code as “return View();”

- In create a controller; a new folder will be created under “Views” named as “devices”.

4. Add a View:

- Finally for adding a view, right click on newly created “Employee” folder under views, choose “Add”, then “MVC 5 View Page”. Specify the name for the view “Index” as in figure (6.13):

Figure (6.13): choose view.

- A new file with the name “Index.cshtml” will be added under “Views->Employee” folder. added meaningful some text to this page as shown in figure(6.14):

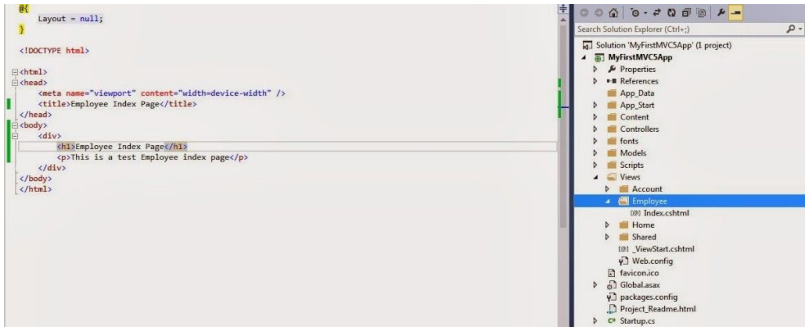


Figure (6.14): add view.

The code of adding the view illustrate at appendixes of the project in appendix (B, c).

All three steps repeating for all data that creating a simple ASP.NET MVC 5 application. To run the application, click CTRL + F5. Result will be as follows:

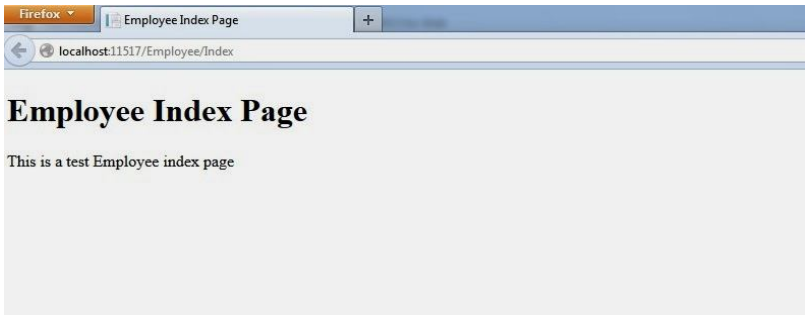


Figure (6.15): run the application.

After that named the URL in browser to http://localhost:8082/and press enter, still the output remains the same, which explain the last step to build the architectural pattern of the program.

6.1.3. Build up the user interface:

In designing HTML interface, try to be consistent and predictable in choice of interface elements. Users have become familiar with elements acting in a certain way, so choosing to adopt those elements when appropriate will help with task completion, efficiency, and satisfaction.

Interface elements include but are not limited to:

- Input Controls like checkboxes, radio buttons, dropdown lists, list boxes, buttons, toggles, text fields, date field for example:

  -Radio buttons are used to allow users to select one item at a time as shows in figure (6.16)

Figure (6.16): radio button.

- A date picker allows users to select a date and/or time. By using the picker, the information is consistently formatted and input into the system.

Figure (6.17): date and time picker.

- Navigational Components like breadcrumb, slider, search field, pagination, slider, tags, icons for example:

  - Pagination divides content up between pages, and allows users to skip between pages or go in order through the content.

Figure (6.18): Pagination.

- An icon is a simplified image serving as an intuitive symbol that is used to help users to navigate the system. Typically, icons are hyperlinked.

Figure (6.19): an icons.

- Informational Components like tooltips, icons, progress bar, notifications, message boxes, modal windows for example:

  - A message box is a small window that provides information to users and requires them to take an action before they can move forward.

Figure (6.20): a message box.

6.2. Implementation:

6.2.1. Application of medical devices information in the control program:

Some of the information entered to the medical devices system is illustrate in table (6.1).

Table (6.1): information of devices.

Serial number (S/N)	model	Manufacturer	department	Sort of device	Type of device
CV-2p109577	MEC-2000	Mindary	ICU	Mid risk	Patient monitor
CV-2p109598	MEC-2000	Mindary	ICU		
			ICU		
CV-2B109599	MEC-2000	Mindary	Theatre- surgical unit		
CE-01119779	PM-7000	Mindary	Theatre- recovery		
			Theatre- orthopedic unit		
V2B109594	MEC-2000	Mindary	ER		
2380612	p-600	ATOM	ICU	Mid risk	Infusion pump
31203623	Sk-600	SK	ICU		
31203595	Sk-600II	SK	ICU		
			ICU		
40100382	SK-5002	SK	ICU	Mid risk	Syringe pump
			ICU		
			ICU		
			ICU		
43003682	Synovent E5	Mindary	ICU	High risk	Mechanical ventilator
	Synovent E5	Mindary	ICU		
3737A1214	N1722A	codemoski	ICU	High risk	Dc-shock
101938828152	lifePAK9p	Physio-control	Theatre- surgical unit		
			ER		

First step to entry the system addressed the web browser of a web page in an address barin the browser (http://localhost:8082) and press enter.

The program beginning with confronted window as shows in figure (6.21), consist of an email and password to entering the medical devices system.

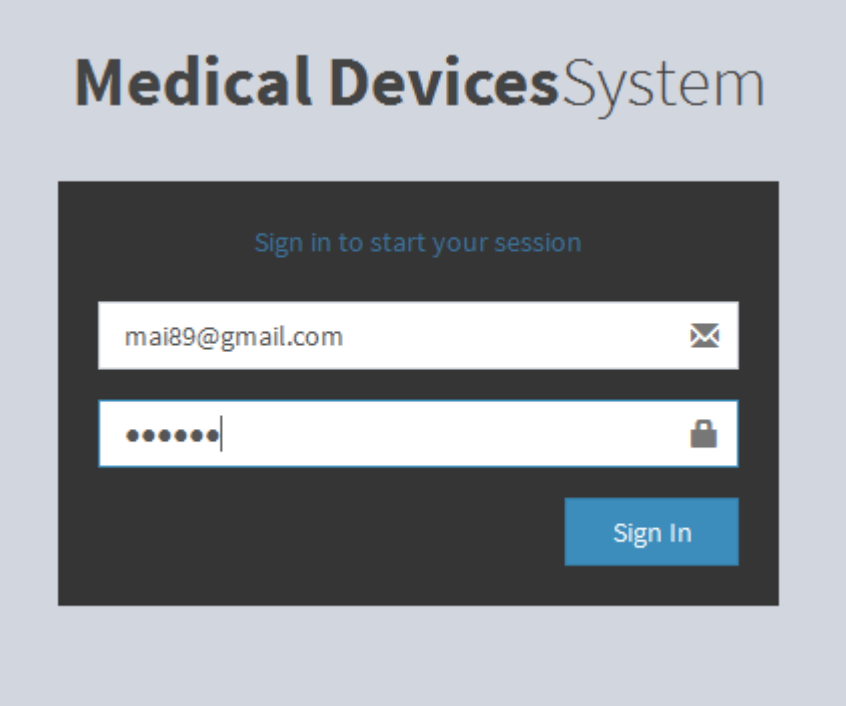


Figure (6.21): interface entry.

The program contains oftwo specifies Information Objects master data and sub-master data.

-The Information Objects are designed in an Object at the left of interface entry organized in a well-defined information of devices as (master data) that choosing in addition step to build a database for devices.

The master data composed of various data that can be mandatory, conditional or optional, those data describe the sort of devices, classification, sub-classification, companies, departments, properties, accessories and spare parts of devices and are grouped in one device that represent as report, as shown in figure (6.22).

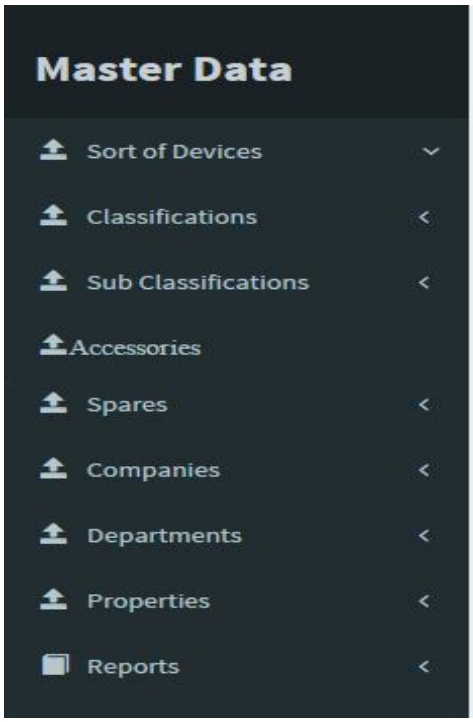


Figure (6.22): master data.

For example to create a master data follow below steps:

- In data master to create sort of device, choose sort of device button, and creation button (+), named the sort and write any note about it and press “create”.

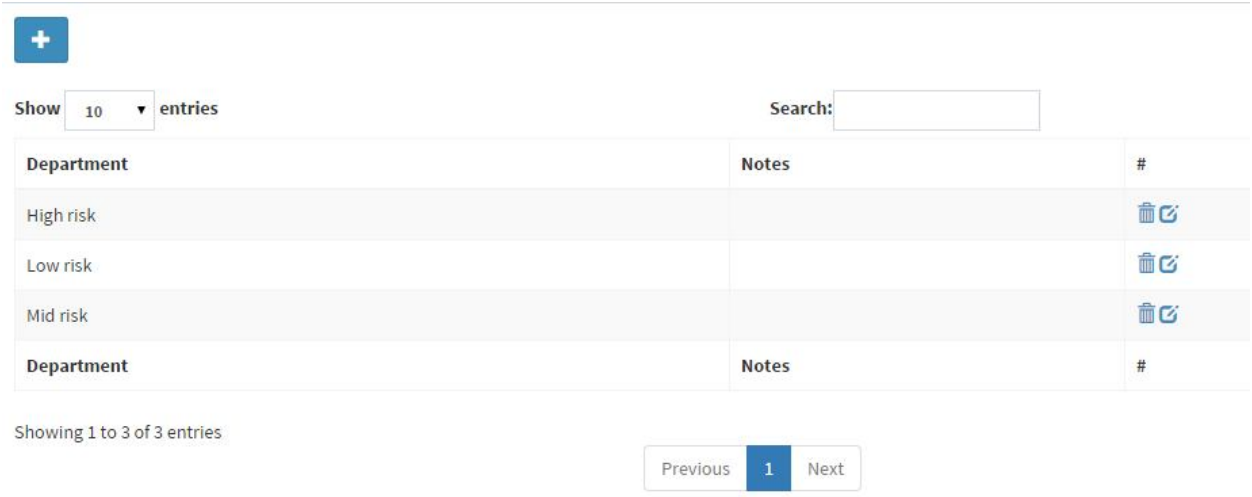


Figure (6.23):first step to creation sort of device.

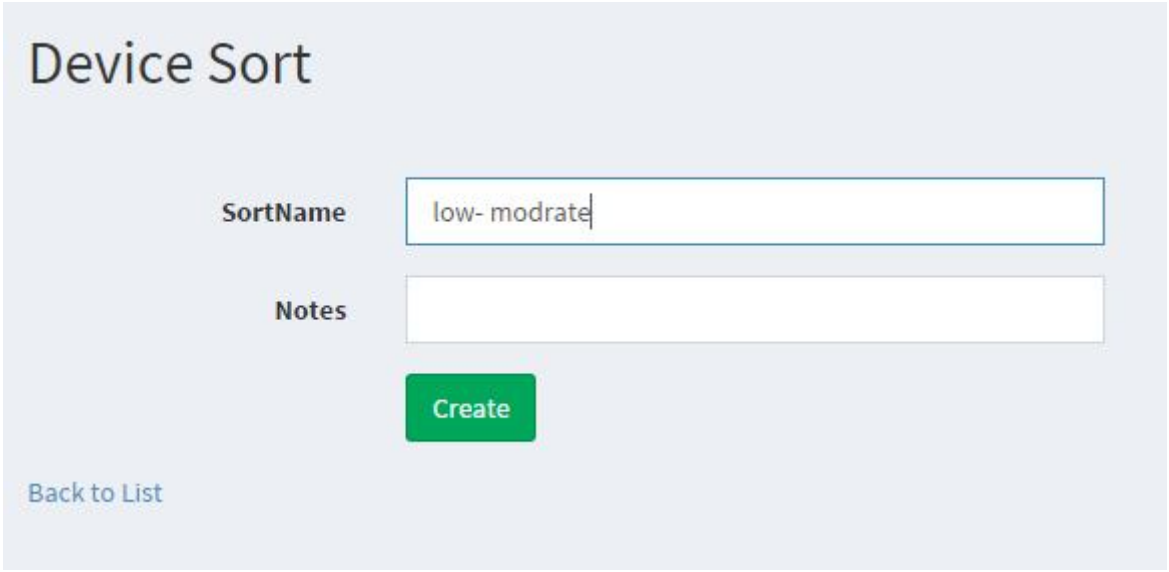


Figure (6.24):named the device sort and create it.

- In data masterto create companies information select “companies” press creation button (+), write the name of company and their information and then press create that will be added to the data base.

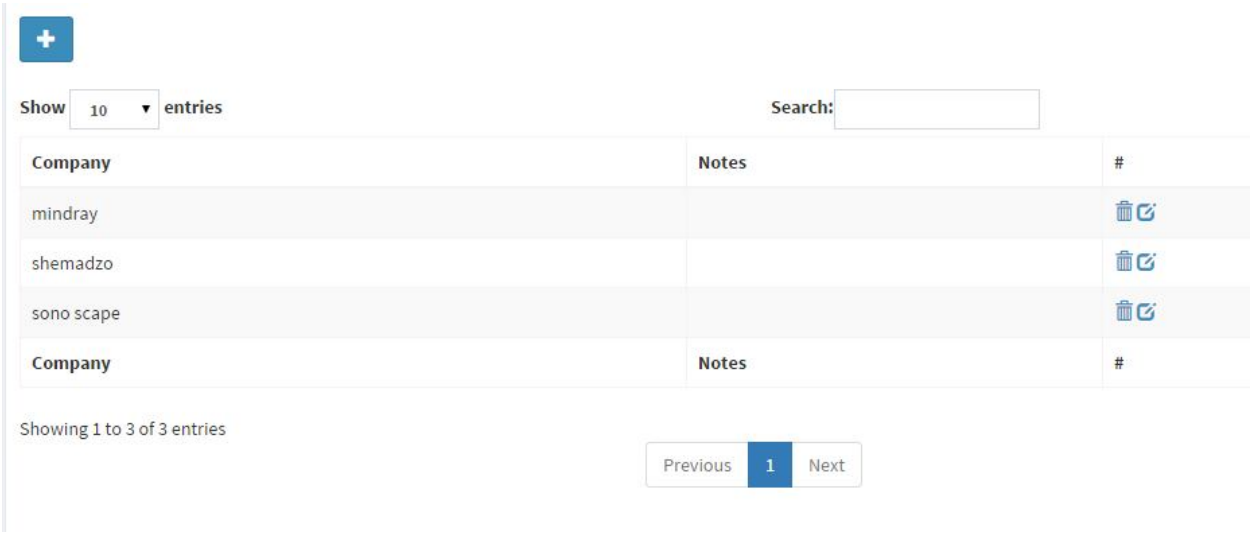


Figure (6.25):first step to create the data of company.

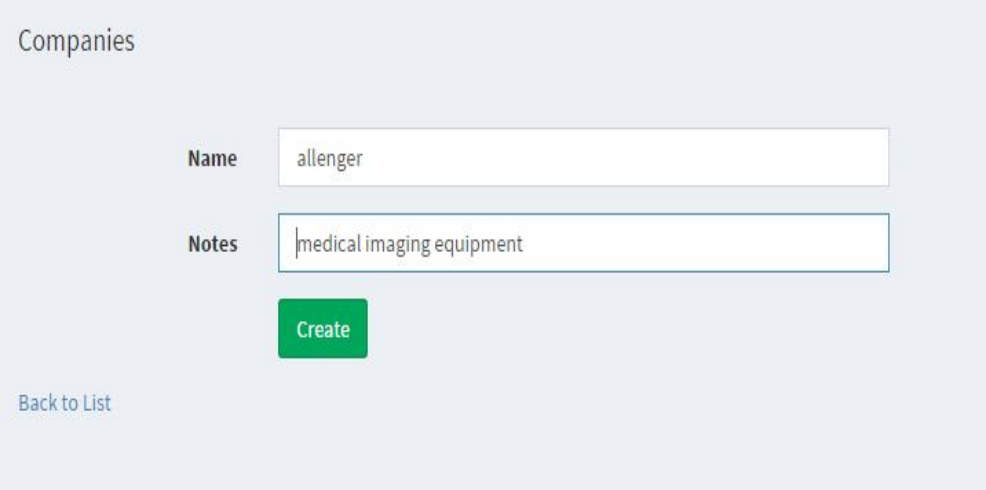


Figure (6.26):named the company.

- Sub-master data that defines as blocks of information persisted in files representing the addition of medical device and it's information objects(properties, spare parts, accessories, troubleshoots and preventive procedure) as shows in figure (6.27).

Figure (6.27): addition of a new device, properties or preventive procedures.

For example to create a sub-master data can follow below steps:

- Select add device

Figure (6.28): add a new device.

- In sub-master datato create a new device press “add device”, creation button (+), write the name of device and select the information of device that saved in master data like sort of device and insert their model and the serial number and then press create.

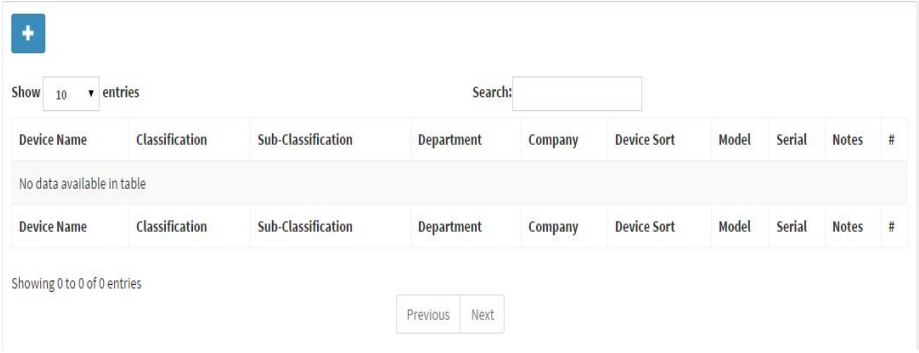


Figure (6.29): first step toadd a new device.

- To create device preventive procedures named the device, the preventive maintenance that it need and the date and all details.

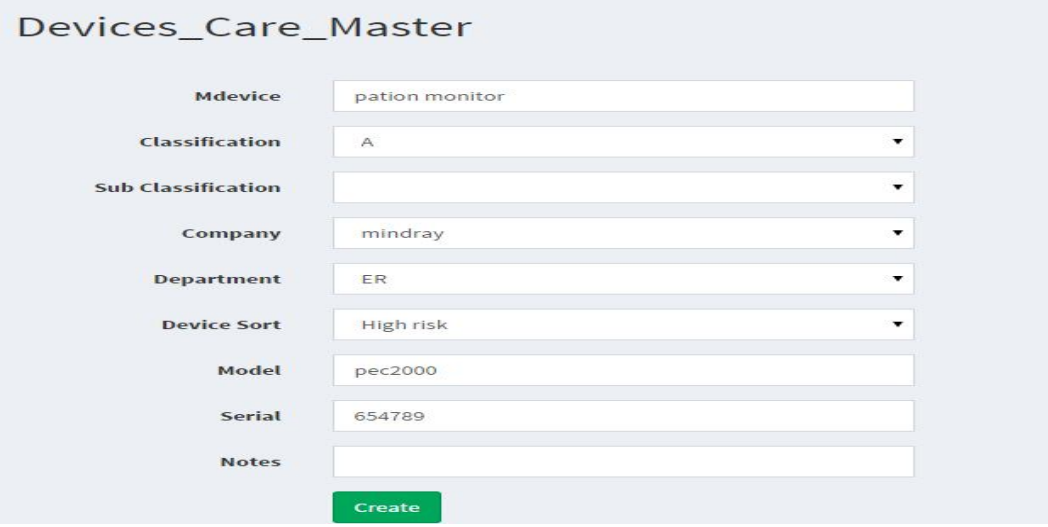


Figure (6.30): named the device and create it.

6.2.2. Application of the program in hospital:

This is the practical part of the study is constructed to experiment the control design and implement an effective program to test and validate it sufficiently, the software component needs to be integrated within the whole existing hospital system or local area network(LAN), LAN can supports connection of multiple computers in a home network to share files and applications in the home, to add anew IP address open start, new connection, open local area connection, right click after that select status, details, keep an IP address then choose link local with IP address, in last step write command with new link that which makes in all PCs are connected together.

After the medical equipment system is established, it can be used in combination with work orders and service history records to identify equipment information, maintenance and spare parts,training on operating of the program is essential, it is important to note the training of using the program may be for either or both technical and clinical staff. Where clinical staff members are expected to maintain and update equipment inventory information.

Additionally, the arrival of a new piece of equipment typically sparks a series of training activities within the health-care facility, such as appropriate use and technique (required for clinical staff but also useful for maintenance staff), general maintenance, proper cleaning and storage of the equipment.

Alrawdahospital has implemented the medical devices system that can be some sort of quality management system, this system track and record all training performed (equipment-related or otherwise) and restrict equipmentuse and maintenance to those staff members who have been trained on. In this case, equipment usage will be managed in conjunction with this system, the software component integrated within the local area network (LAN).

Figure (6.31): training of using the medical devices system.

A maintenance unit in biomedical department is investigated with initial source and alternative sub-source for evaluating the medical Devices needs service.

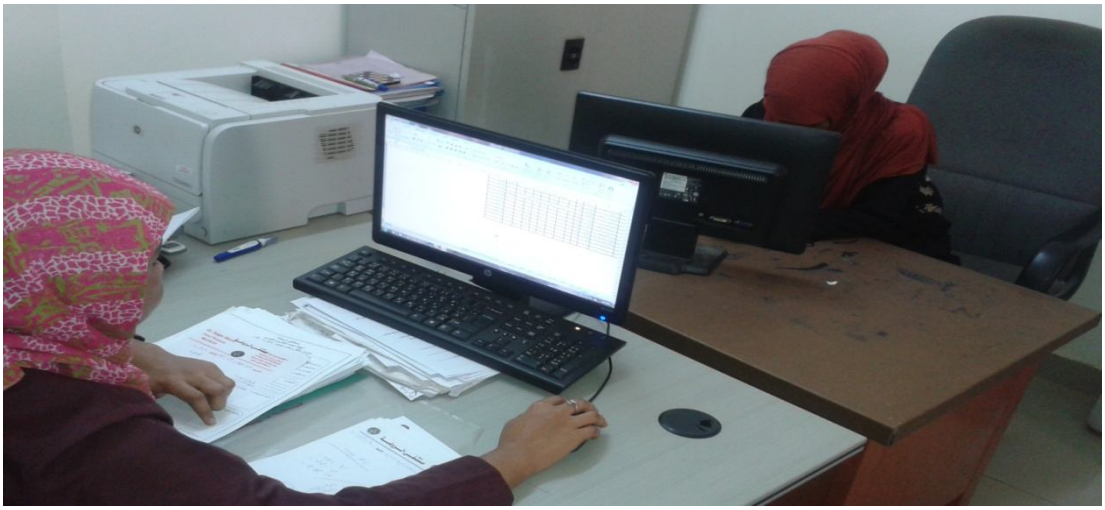


Figure (6.32): The software component integrated within the local area network.

CHAPTER SEVEN

7. DISCUSSION AND RESULTS

This section describes and discusses the results that obtained from the applying of the medical devices system, which illustrated before on the previous section.

Once the control program has been established, it can be a very helpful tool within the clinical engineering department and the health-care facility as a whole. This section illustrates the value of availability of centralized of medical equipment information.

The equipment program can be used to assist in forecasting a variety of budgets. By considering current equipment values, performing a needs assessment, identifying equipment that needs to be replaced, and determining the expected lifetime of equipment, capital budgets can be forecast for the coming years for the purchase of new equipment.

Annual service and operating costs associated with the equipment inventory can be used to plan for future annual budgets. Additionally, spare parts and consumables usage can be used to forecast and plan for future stock planning and budgeting.

A workshop with adequate space and the appropriate tools and test equipment is essential to keep equipment running safely and in good order. The control program is an important input in determining the tools and test equipment required for maintenance and the budget required for acquiring, calibrating and maintaining the instruments.

Depending on the technical requirements of the medical equipment maintained in the program, the workshop may require various areas dedicated to different types of work.

Knowledge of the equipment available can help the clinical engineering department determine the staffing and skill-set needed to keep the equipment in good running order.

In addition, the system of equipment will enable the organizational management to hire doctors, nurses, technicians and so on with the skill-set required to effectively operate the equipment. In most settings, clinical staff will also be responsible for performing various degrees of maintenance, including calibration, cleaning, storage and basic tasks such as changing filters and bulbs. In resource-limited settings, equipment users may also play a greater role in information management.

At times, support from external service providers will be required to undertake the service and repair activities for medical or test equipment. This is often the case for highly specialized equipment and equipment under warranty. The applied program can help identify which equipment needs external service and can also assist in determining the budget required and available for such service.

It is important for the clinical engineering department to track all activity performed by external service providers and to ensure that all records of service performed are added to the equipment history file to maintain an accurate record.

A medical equipment system can help identify the spare parts and consumables required to keep the equipment running. Spare parts and consumables inventories alert the team to order stock so that current reserves are not depleted and service is not stopped.

The main functions here are to determine usage rates (number of parts/time) and to establish a reorder level that is sufficient to maintain service during the time required to order and obtain the new parts. When managed correctly, item stock levels are never depleted and service continues uninterrupted.

All equipment has an expected lifetime and will eventually need to be replaced or disposed of. Service histories associated with inventory items can be assessed to determine when equipment is no longer serviceable, relevant, safe or cost-effective. Over time, trends can help to identify the expected lifetime for equipment and cost-effectiveness (or lack of) to keep a piece of equipment in service.

This information can help to develop policies for the replacement or disposal of equipment. Subsequently, this information can be used to prepare budgets for new capital purchases, repair services and so on.

Knowledge of equipment quantity and type can feed into planning for disasters and emergencies to determine the number of patients that can be accepted by a facility during such events.

The implementation of medical devices system as a control program, provide some opportunities to analyze the current situation of equipment for improving the performance. Therefore, the better organizational structures are designed for the system with many health care facilities goals as higher level of patient satisfaction.

CHAPTER EIGHT

8. CONCLUSION AND RECOMMENDATION

8.1. Conclusion:

Theaim of this work is to design and implement a computerized system for controlling medical devices system.The data has been collected from different specialized sources (text books, references and websites) and exploratory visits then it has been processed by statistical analysis to get suitable view for designing.

After applying the control program of medical devices and insert the information of equipment, the program has been performed, then the benefits have been extracted in a good results, this step has followed by trained and educate the medical staff to accessthe best results and that can facilitate the flow of work at all hospital, also provide high accuracy in detecting any defects or needs.

So it can be concluded that the medical devices system is suitable for tracing information equipment, and it has been useful for the management control at the whole hospital departments.

8.2. Recommendation:

- Increase the speed of program to get quick results.
- Try to process any differences in the requirements toresolveautomatically.
- Enhancement the managing infrastructure in the architectural pattern.
- Request from staff for calling the clinical engineer included in program.
- Implement a control program in a wide area network.
- Professional software can apply for continuous improvement in real-time feedback.
- Planning for spare parts and consumables orders.

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Appendixes

Appendix (A)

Form of Questionnaire:

Questionnaire of quality management in medical equipment

This questionnaire will help my research to explain that the Control program of medical instrumentation and equipment is an essential part of an effective health care technology management system.

1. A database is a collection of related data organized in a manner intended to be accessed by multiple users for varied purposes. Database controls are designed to ensure that activities related to the security, integrity, accountability and recoverability of the database are controlled.
- Does the hospital have Database documentation for medical devices?

☐ **Yes** ☐ **No**

---

2. When we design a program to be a single centralized location for all data concerned to medical devices, that facilitate the flow of work and provide high accuracy Control managing and risks.

☐ **Agree** ☐ **Disagree**

---

3. Do you think the control design program can control preventive and maintenance for devices as much?

☐ **25%** ☐ **50%** ☐ **75%** ☐ **100%**

---

4. The System development the process of computerized applications in hospital that consists of several phases. Each phase has objectives, processes and products, that provide cost control.

☐ **Agree** ☐ **Disagree**

---

5. Did the hospital procedures are developing in getting new devices?

☐ **Yes** ☐ **No**

6. Computer program control is designed to ensure that equipment's continue to function consistently, as planned. They include controls over the use of the correct data, calibration, preventive, and maintenance as source of flow of work, and the proper performance of all function concerned with devices by operators, particularly which controls issues when a problem occurs.

-is that help the medical staff to support health care?

☐ **Rarely** ☐ **Sometimes** ☐ **Often**

---

7. Are workloads properly managed by using medical devices and their accessory so it needs schedules processing to ensure that all jobs are processed and that deadlines and priorities are considered?

☐ **A lot** ☐ **A little**

---

8. A **Medical devices contains** instruments, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. And **Medical equipment that contains** Medical devices requiring calibration, maintenance, repair, user training, and decommissioning – activities usually managed by clinical engineer.

- The program contain medical tools, devices and equipment's,Are we making procedures for limiting access to the database source and operating software?

☐ **YES** ☐ **NO**

---

9. Have there been any complaints or allegations of non-compliance with professional standards, regulatory and legal requirements of the design control of quality systems in the past yearin our country?

☐ **Yes** ☐ **NO**

---

10. Management provides guidance for the development and maintenance of devices and complete procedures in hospital?

☐ **Strongly agree** ☐ **Agree** ☐ **Strongly disagree** ☐ **Disagree**

Appendix (B)

The project creates codes in architectural pattern step as below:

a) **Model code:**

```
public partial class MDE_001_Devices
  {
     public int ID { get; set; }
     public string Device_Name { get; set; }
     public string Notes { get; set; }
  }
```

b) **Controller** code:

```
public class MDE_001_DevicesController : Controller
  {
     private FMD db = new FMD();
     // GET: MDE_001_Devices
     public ActionResult Index()
     {
        return View(db.MDE_001_Devices.ToList());
     }
     // GET: MDE_001_Devices/Details/5
     public ActionResult Details(int? id)
     {
```

```
            if (id == null)
            {
                return new HttpStatusCodeResult(HttpStatusCode.BadRequest);
}
MDE_001_Devices mDE_001_Devices = db.MDE_001_Devices.Find(id);
if (mDE_001_Devices == null)
            {
                return HttpNotFound();
            }
            return View(mDE_001_Devices);
        }
        // GET: MDE_001_Devices/Create
        public ActionResult Create()
        {
            return View();
        }
        // POST Devices/Create
        // To protect from overposting attacks, please enable the specific properties you want to bind to, for
        // more details see http://go.microsoft.com/fwlink/?LinkId=317598.
        [HttpPost]
```

```
    public ActionResult Create([Bind(Include = "ID,Device_Name,Notes")]
MDE_001_Devices mDE_001_Devices)
    {
        if (ModelState.IsValid)
        {
db.MDE_001_Devices.Add(mDE_001_Devices);
db.SaveChanges();
            return RedirectToAction("Index");
        }
        return View(mDE_001_Devices);
    }
    // GET: MDE_001_Devices/Edit/5
    public ActionResult Edit(int? id)
    {
        if (id == null)
        {
            return new HttpStatusCodeResult(HttpStatusCode.BadRequest);
}
MDE_001_Devices mDE_001_Devices = db.MDE_001_Devices.Find(id);
if (mDE_001_Devices == null)
        {
            return HttpNotFound();
```

```
        }
        return View(mDE_001_Devices);
    }
    // POST: MDE_001_Devices/Edit/5
    // To protect from overposting attacks, please enable the specific properties you want to bind to, for
    // more details see http://go.microsoft.com/fwlink/?LinkId=317598.
    [HttpPost]
 public ActionResult Edit([Bind(Include = "ID,Device_Name,Notes")] MDE_001_Devices mDE_001_Devices)
    {
        if (ModelState.IsValid)
        {
            db.Entry(mDE_001_Devices).State = EntityState.Modified;
            db.SaveChanges();
            return RedirectToAction("Index");
        }
        return View(mDE_001_Devices);
    }
    // GET: MDE_001_Devices/Delete/5
    public ActionResult Delete(int? id)
    {
```

```
            if (id == null)
            {
                return new HttpStatusCodeResult(HttpStatusCode.BadRequest);
}
MDE_001_Devices mDE_001_Devices = db.MDE_001_Devices.Find(id);
if (mDE_001_Devices == null)
            {
                return HttpNotFound();
            }
            return View(mDE_001_Devices);
        }

        // POST: MDE_001_Devices/Delete/5
        [HttpPost, ActionName("Delete")]
        [ValidateAntiForgeryToken]
        public ActionResult DeleteConfirmed(int id)
{
MDE_001_Devices mDE_001_Devices = db.MDE_001_Devices.Find(id);
            db.MDE_001_Devices.Remove(mDE_001_Devices);
db.SaveChanges();
            return RedirectToAction("Index");
        }
```

}

c) **View** code:

```
@model IEnumerable<MedicalEquipments.Models.MDE_001_Devices>

<div class="col-xs-12">

<div class="box">

<div class="box-header">

<a href="~/MDE_001_Devices/Create" class="dialog btn btn-success" data-modal="" id="btnCreate">

<span class=" plus"></span>

</a>

</div>

<!-- /.box-header -->

<div class="box-body">

<table id="example2" class="table table-bordered table-striped">

<thead>

<tr>

<th>Device Name</th>

<th>Notes</th>

<th>#</th>

</tr>

</thead>
```

```
<tbody>
@foreach (var item in Model)
        {
<tr>
<td>
@Html.DisplayFor(modelItem => item.Device_Name)
</td>
<td>
@Html.DisplayFor(modelItem => item.Notes)
</td>
<td>
<a href="~/MDE_001_Devices/Delete/@item.ID" title='حذف'><span class='glyphicon glyphicon-trash'></span></a>
<a href="~/MDE_001_Devices/Edit/@item.ID" title="تعديل" class="dialog" data-modal='' id="btnEdit">
<span class="glyphicon glyphicon-edit"></span>
</a>
</td>
</tr>
   }
</tbody>
<tfoot>
```

```
<tr>
<th>Device Name</th>
<th>Notes</th>
<th>#</th>
</tr>
</tfoot>
</table>
</div>
<!-- /.box-body -->
</div>
</div>
```