Brunel University London

College of Engineering, Design and Physical Sciences

Department of Mechanical and Aerospace Engineering

DESIGNING A DECISION SUPPORT SYSTEM FOR IMPROVING MEDICAL DEVICES MAINTENANCE IN SAUDI ARABIA

A thesis submitted for the degree of Doctor of Philosophy

By

Hamad Albadr

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ABSTRACT

According to the World Health Organisation, up to 70% of the medical devices in the developing world are broken, and up to 96% of them are out of service. Medical devices are not only essential for safe and effective patient care but also has a significant impact on the income of healthcare organisations. So, medical devices maintenance requires careful supervision by healthcare administrators who may not have the technical background to understand all the relevant factors. This research aims to design a decision support system for improving medical devices maintenance in Saudi Arabia to help the decision makers on all the maintenance stages needs. Also, to determine the parameters involved in medical devices maintenance in Saudi Arabia, and to identify the best international practice experiences in medical devices maintenance. The research had reviewed theoretical background for medical devices maintenance followed by reviewing the previous studies in good practices in medical devices maintenance through gathering good national practices from Saudi Arabian organisations, good international practices from international organisations, good postgraduates' dissertations include master's and PhD thesis and reviewing good technical academic papers. The methodology of the research used the descriptive approach through main seven steps: First, designing a survey of the clinical engineering department in Saudi Arabia that has an overview of medical devices maintenance in Saudi Arabian hospitals. The survey contains four main parts: general Information, structure, personnel, responsibilities, and resources. Second, applying the survey and collected the designated information. Third, designing a questionnaire of evaluating current management performance for medical devices maintenance in Saudi hospitals through the nine main stages of medical devices maintenance life cycles as follows: 1. Planning, 2. Acquisition 3. Delivery and Incoming Inspection; 4. Inventory and Documentation 5. Installation, Commissioning, and Acceptance 6. Training of Users and Operators 7. Monitoring of Use and Performance 8. Maintenance 9. Replacement or Disposal. Forth, validating the questionnaire for consistency and stability. Fifth, applying the questionnaire and collected the designated information. Sixth, designing the proposed decision support system. (Chapter 6). Finally, validating the proposed decision support system. The research outcomes contain two main contributions; firstly, designing a questionnaire to evaluate the clinical engineering department services through 64 clinical engineering program indicators. Second, developing the proposed decision support system that had been validated by experts

in the field to make sure the system is suitable to evaluating current management performance for medical devices maintenance in Saudi Hospitals including the validation study for the system. The proposed decision support system aims to facilitate the introduction of grades, and the extraction of averages and reporting system is designed using Microsoft Access, where the system has four main features: setting, evaluate reports, and resources. Finally, the study came up with some recommendations to improve medical devices maintenance in Saudi Arabia.

DECLARATION

I declare that this thesis has not been accepted in substance for any degree and it is not submitted in candidature for any other degree. It is the result of my independent research except where otherwise stated.

RESEARCH ACTIVITIES DURING THE STUDY

This thesis contains the following material that had been published or submitted for publications because of this research:

1. Albadr, H. (2018) *Medical Staff Satisfaction on Medical Devices Calibration in Saudi Hospitals*, Riyadh, Saudi Arabia: The Saudi Food and Drug Authority Annual. 25-27/11/2018.
2. Albadr, H. (2016) *Medical Devises Maintenance in Saudi Arabia: Reality and Challenges*, 4th Biomedical Engineering Conference, Riyadh: Ministry of Health. 16/5/2016.
3. Albadr, H. (2015) *Calibrating Medical Devices in Saudi Arabian Hospitals: Reality and Challenges*, The First Gulf Metrology Forum, Doha, Qatar: Gulf Organization for Industrial Consulting (GOIC). 14-15/12/2015.
4. Albadr, H. (2015) *Designing a Decision Support System for Improving Medical Devices Maintenance in Saudi Arabia*", Brunel Festival showcase 2015, London: Brunel University London. 20-21/5/2015
5. Albadr, H. (2015) *Designing a Decision Support System for Improving Medical Devices Maintenance in Saudi Arabia*, 12th Annual Research Multilingual Conference on Advancement in Business, Education, Science and Technology (ARCBEST – 2015), American Academic & Scholarly Research Center (AASRC) London. 20-21/5/2015.
6. Albadr, H. (2015) *Designing a Decision Support System for Improving Medical Devices Maintenance in Saudi Arabia*", Research Student Conference, London: Brunel University London. 17-18 /3/2015.
7. Albadr, H. (2014) *The Quality of Biomedical Engineering Technology Training in Saudi Arabian Technical Colleges*, 26th International Business Research Conference, Imperial College, London, World Business Institute, Australia. 7 – 8 /4/2014.
8. Albadr, H. (2014) *Training of Biomedical Engineers in Saudi Arabian Hospitals: Reality and Expectations*", 26th International Business Research Conference, London: World Business Institute, Australia. 7–8 /4/2014.

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Last, but not least, my appreciation is extended to all who have participated in my research and who facilitated the research process by contributing to my data collection.

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ABBREVIATIONS

AAMI Association for the Advancement of Medical Instrumentation

AASRC American Academic & Scholarly Research Centre

ACCE American College of Clinical Engineering

AFMLO Air Force Medical Logistics Office

AHA American Hospital Association

AI Artificial Intelligence

ASHE American Society for Healthcare Engineering

BMET A biomedical engineering/equipment technician/technologist

CBAHI Central Board of Accreditation for Healthcare Institutions

CBM Condition Based Maintenance

CBR The Case-based Reasoning

CE Clinical Engineering or Clinical Engineer

CED Clinical Engineering Department

CFR Constant Failure Rate

CM Corrective Maintenance

CMMS Computerised Maintenance and Management System

COSR The cost-of-service ratio

CT Computed Tomography

DBE Directorate of Biomedical Engineering

DBMS a database management system

DFID the UK Department for International Development

DSS Decision support systems

EC evidence of compliance

ECRI Emergency Care Research Institute

EMI Electro Magnetic Interference

FDA Food and Drug Administration

GHTF the Global Harmonization Task Force

GOIC Gulf Organization for Industrial Consulting

HTM Healthcare Technology Management

ICU Intensive Care Unit

ILO the International Labour Organisation

IPM Inspection and Preventive Maintenance

ISO the International Organization for Standardization

JCI Joint Commission International

JSDT the Japanese Society for Dialysis Therapy
KPI Key Performance Indicator
MBMS Model Base Management System
MDP Markov Decision Process
MHLW The Ministry of Health, Labour and Welfare in Japan
MHRA Healthcare Products Regulatory Agency
MOH Ministry of Health
MTA Medical technology assessment
MTBF Mean Time Between Failures
MTTF Mean Time to Failures
OEM Original Equipment Manufacturer
OR Operating Room
OVR Occurrence Variance Report
PA Performance assurance
PM Preventive Maintenance
PREMO Preventive Maintenance Optimisation
PSOI Primary Source of Information
R&D Research and Development
RCM Reliability Maintenance Centre
RT Repair Time
SCHS Saudi Commission for Health Specialties
SFDA Saudi Food and Drug Authority
SM Scheduled Maintenance
SPI Safety and Performance Inspection
SPSS Statistical Package for Social Sciences
TPLC The Total Product Life Cycle
WHO World Health Organization

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CHAPTER 1: INTRODUCTION

1.1 Overview

Technological innovation has shaped every aspect of modern lives, especially in medicine and healthcare services. The evolution of technology provides a wide range of diagnostic and treatments. The importance of this growth process has been the establishment of the modern hospital as the centre of a technologically sophisticated healthcare system. Since technology has a dramatic impact on medical care, engineers have become personally involved in many medical projects. Biomedical engineering, which emerged in medicine and engineering, has aided against illness and disease by providing modern tools to utilise research, diagnosis, and treatment. Biomedical engineers try to find new solutions for the severe problems confronting modern society.

The term medical devices cover a wide range of equipment, from simple tongue depressors to hemodialysis machines. They cost governments a significant amount of money. The world market of medical devices in 2015 has reached US$ 311.23 billion. The leading producers and exporters of high quality and high-tech medical instruments and equipment are the US as the most significant single market, which alone accounts for nearly 45% (more than $140 billion) out of the entire marketplace, The rest of the world shares 33% of the market. (US International Trade Administration, 2016).

In 2000, the estimated one and a half million different medical devices available on the market. With innovation and the quick advancement of technologies, medical devices are currently one of the fastest growing industries, but many countries absence accesses to high-quality devices and equipment (WHO, 2003).

Also, in a modern hospital, the complicated and expensive technology encourage the healthcare staff for more education and training that has gained a great deal of attention is projected to grow exponentially. (Enderle, 2002).

According to The American College of Clinical Engineering (ACCE), Clinical Engineering is the field of engineering that supports and advances patient care by applying engineering and management skills to healthcare technology (ACCE, 1992). The purpose of this chapter is to provide the reader with a broad overview of medical

devices maintenance background, highlight the essential research background that includes defining the research problem, the research rationale, the research aims, research questions, the research limitations, and the research terminologies.

1.2 Research Problem

The primary clinical engineering activities are dealing with medical device inspection, maintenance, and repair. Clinical engineering has emerged, mainly in response to the essential services of cost control, utilisation optimisation, regulatory requirements, patient safety and human error awareness, and increasing complexity of the technological environment. (Dyro, 2004).

The World Health Organisation stated at the Medical Device Meeting in the fall of 2010 that “about 70% of the more complex medical devices do not function when they reach their destination.” Other papers state that up to 96% of medical equipment is out of service. (Perry and Malkin, 2011)

According to The Joint Commission International (JCI), there are 98 alarm-related events had reported over a three-and-a-half-year period, with 80 of those events resulting in death and 13 in permanent loss of function. (ECRI, 2013). Also, the Food and Drug Administration (FDA) had reported that a total of 980 device-related deaths in 1998 stated that under the requirements of the Safe Medical Devices Act medical device manufacturers said that. (Gardner and Flack, 1999). In a presentation to the Association for the Advancement of Medical Instrumentation a representative of the FDA Centre for Devices and Radiological Health stated that one-third of the 80,000 incident reports it receives annually might involve medical equipment “user error.” Medical technology is an integral component of the healthcare delivery system. Efforts to improve patient safety and the quality of healthcare delivery must consider the omnipresence of medical technology. (AAMI, 2000).

World Health Organisation (WHO) had suggested a strategy and proposed action concerning maintenance of hospital and medical equipment that because of reporting some evidence. There is 30–50% additional cost for extra spare parts and extra maintenance workload because of the lack of standardisation; there is 20–40% of equipment remains under-utilised or unused because the purchase of sophisticated equipment for which operating, and maintenance staff have no skills. Also, there is a

loss of 30–80% of the potential lifetime of equipment because improper use of equipment by operating and maintenance staff who lack the necessary training. (Kaur, 2005).

In many countries, medical devices maintenance, not only, costs billion dollars every year from the limited national income, but also, not handled professionally, thus creating an extreme health risks to medical workers, patients, and the environment. To the best of the author's knowledge, there has been no comprehensive effort to understand how medical devices are managed by hospitals, clinics, and other healthcare facilities. Investigation of medical devices maintenance problems is the first step in health risk reduction. When medical devices maintenance problems cannot have eliminated at the source**.**

Most of the knowledge of approaches to medical devices maintenance there has been no full-scale quantitative and qualitative analysis of medical devices maintenance problems in the kingdom. It is essential to come up with a bright, comprehensive plan for improving medical devices maintenance in Saudi Arabia to carry out these responsibilities by applying such the proposed decision support system to enhance medical devices maintenance activities.

The problem that the research is addressing is designing a decision support system for Improving medical devices maintenance in Saudi Arabia.

1.3 Research Importance

Research gets its importance from the following:

1. Identifying the parameters involved in medical devices maintenance in Saudi Arabia.
2. Gathering the best good practice experiences in medical devices maintenance.
3. Designing a tool using the proposed decision support system to help the decision makers on the maintenance stage needed.

1.4 Research Aim and Objectives

The research aims to improve medical devices maintenance in Saudi Arabian Hospitals. This aim achieves through these three objectives:

1- Identifying the parameters involved in medical devices maintenance in Saudi Arabia.
2- Identifying good practice experiences in medical devices maintenance.
3- Designing the proposed decision support system to help the decision makers on the maintenance stages needed.

1.5 Research Questions

1. What are the parameters involved in medical devices maintenance in Saudi Arabia?
2. What are the best international practice experiences in medical devices maintenance?
3. What is the proposed decision support system for improving medical devices maintenance in Saudi Arabia?

1.7 Research Terminologies

1.7.1 Medical Device

According to World Health Organisation (WHO, 2003), “Medical device” means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article. It intended by the manufacturer to be used, alone or in combination, for human beings. It may apply for one or more of the specific purposes of: (1) diagnosis, prevention, monitoring, treatment or alleviation of disease or (2) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or (3) investigation, replacement, modification, or support of the anatomy or of a physiological process or (4) supporting or sustaining life or (5) control of conception or (6) disinfection of medical devices or (7) providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such methods.

Also, the Office of the Legislative Counsel (2014) defines medical device as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. (Office of the Legislative Counsel, 2014).

1.7.2 Medical Devices Maintenance

Medical equipment maintenance is all activities that include (1) inspection and preventive maintenance (IPM), and (2) corrective maintenance (CM). IPM includes all scheduled activities that ensure equipment functionality and prevent breakdowns or failures. Performance and safety inspections are straightforward procedures that verify proper functionality and safe use of a device. Preventive maintenance (PM) refers to scheduled activities performed to extend the life of a device and prevent failure (i.e., by calibration, part replacement, lubrication, cleaning, etc.). Inspection can be conducted as a stand-alone activity and in conjunction with a PM to ensure functionality; this is important, as PM can be invasive in that components are removed, cleaned or replaced. (World Health Organisation, 2011).

1.7.3 Decision Support System

An interactive computer-based system designed to help a person or a group of people to make decisions in a specific domain. (Negnevitsky, 2005)

1.8 Research Methodology

The methodology of the research used the descriptive approach through main seven steps: First, designing a survey of the clinical engineering department in Saudi Arabia that has an overview of medical devices maintenance in Saudi Arabian hospitals. The survey contains four main parts: general Information, structure, personnel, responsibilities, and resources. Second, applying the survey and collected the

designated information. Third, designing a questionnaire of evaluating current management performance for medical devices maintenance in Saudi hospitals through the nine main stages of medical devices maintenance life cycles as follows: 1. Planning, 2. Acquisition 3. Delivery and Incoming Inspection; 4. Inventory and Documentation 5. Installation, Commissioning, and Acceptance 6. Training of Users and Operators 7. Monitoring of Use and Performance 8. Maintenance 9. Replacement or Disposal. Forth, validating the questionnaire for consistency and stability. Fifth, applying the questionnaire and collected the designated information. Sixth, designing the proposed decision support system. (Chapter 6). Finally, validating the proposed decision support system.

1.9 Structure of the Thesis

The student intends to organise the thesis into seven chapters as follows:

Chapter 1: Introduction with nine sections as follows: - Overview - Research Problem - Research Importance - Research Aim and objectives -Research Questions - Research Terminologies- Research Methodology- Research Terminologies - Structure of the thesis.

Chapter 2: Theoretical Background with three sections as follows :Overview - Medical Devices Maintenance - Decision Support System.

Chapter 3: Previous Studies in Good Practices in Medical Devices Maintenance. This chapter includes good national practices from Saudi Arabian organisations, good international practices from international organisations, postgraduates' dissertations include master's and PhD thesis, and Technical academic papers.

Chapter 4: Methodology of research with four sections as follow: designing a survey of the clinical engineering department in Saudi Arabia (Appendix-1) that includes an overview of medical devices maintenance in Saudi Arabian hospitals. The survey contains from four main parts: General Information - Structure, Personnel, Responsibilities, and Resources - Designing a questionnaire of evaluating current management performance for medical devices maintenance in Saudi hospitals (Appendix-2) to identify the parameters that involve in medical devices maintenance in

Saudi Arabian hospitals - Designing the proposed decision support system. (Chapter 6) - Validating the proposed decision support system. (Chapter 6).

Chapter 5: Study Results and Analysis: The research outcomes contain four contributions; first, the study has collected valuable information about clinical engineering departments from 23 hospitals in Riyadh, Saudi Arabia. Second, designing a questionnaire to evaluate the clinical engineering department services through 64 clinical engineering program indicators. Third, developing the proposed decision support system through 64 clinical engineering program indicators that had been validated by experts in the field to make sure the system is suitable to evaluating current management performance for medical devices maintenance in Saudi Hospitals.

Chapter 6: A Proposed Decision Support System: the proposed decision support system including the validation study for the proposed decision support system. The Proposed Decision Support System aims to facilitate the introduction of grades, and the extraction of averages and reporting system is designed using Microsoft Access, where the system has four main features: setting, evaluate reports, and resources.

Chapter 7: As a summary of the chapter, in this chapter, a description of the conclusion and recommendations of the study with three sections an overview, the conclusion, and the recommendations

References and Appendixes

CHAPTER 2: THEORETICAL BACKGROUND

2.1 Overview of Medical Devices Maintenance

2.1.2 Introduction

The healthcare delivery system is going through a transition that is driven by four primary forces: Budget, structure, technology, and social expectations. (David, Judd, and Zambuto, 2004). As modern engineering involves the application of scientific techniques, theories, and technology for the solution of societal needs, biomedical engineering had been developed in healthcare facilities around the world over the last four decades of the twentieth century. There was a full recognition in professional and government circles of the rapid technological increase that affected society in general and healthcare.

Nowadays, the healthcare delivery system consists of a very complex environment from facilities, equipment, materials, and some human interventions and involvements with patients of various ages and conditions, trained staff, and the wide variety of medical technology converge. This complicated situation leads to high risk when qualified professionals for monitoring, controlling, improving, and educating all entities involved do not correctly integrate programs.

Medical technology supports medical specialist to get involved through joined connections with their patients in a cost-effective, efficient, and safe manner. The field of biomedical engineering has developed as the discipline of engineering that accomplishes the need to manage the distribution of medical technology and to integrate it appropriately with desired clinical practices. (Bronzino, 2000)

Medical devices maintenance not only costs billions of dollars every year from the limited national income, but are also not handled professionally, thus creating a high health risk to medical workers, the patients, and the environment (Barry, 1986). In this case, a comprehensive effort to understand how medical devices managed by hospitals, clinics, and other healthcare facilities.

Because, medical technology is an integral component of the healthcare delivery system, high hard work to expand patient safety and the quality of healthcare delivery

that must consider the omnipresence of medical technology. (AAMI, 2000). All devices carry a certain degree of risk and could cause problems in specific circumstances. Many medical devices problems cannot be detected until extensive market experience is improved. For example, an implantable device may fail in a manner that was not predictable at the time of implantation; the failure may reflect conditions unique to specific patients. For other devices, component failure can also be unpredictable or random. The current approach to device safety is to estimate the potential of a device is becoming a hazard that could result in safety problems and may cause harm. (WHO, 2003).

In this chapter, a review for the theoretical background of the study. This contains three sections. This includes three sections; an overview, medical devices maintenance and decision support system and reviewing the background of biomedical and clinical engineering, the functions and the responsibilities of the clinical engineering department, medical devices management that covers medical devices planning, technical asset management, the technology evaluation and procurement, medical devices maintenance. The second section in this chapter covers medical devises maintenance in Saudi Arabia which includes; healthcare in Saudi Arabia, medical devises maintenance and clinical engineering departments in Saudi Arabia, the clinical engineering program indicators. The third section is an overview of decision support systems that include the definition, structure, applications in clinical engineering and medical devices maintenance.

2.1.2 Biomedical Engineering

Biomedical Engineering is a field where concepts from Engineering, Mathematics, Computation, Physics, and Chemistry are used to solve problems in Biology and Medicine. As Biomedical engineering established in 1959 by a group of medical engineers, physicists and physicians met at the 2nd International Conference of Medical and Biological Engineering, in the UNESCO Building, Paris, France, to create an organisation entitled International Federation for Medical Electronics and Biological Engineering. At that time, there were few national biomedical engineering societies and workers in the discipline joined as Associates of the Federation. Later, as national organisations were formed, these societies became affiliates of the Federation. (Carr, 2000). According to The American College of Clinical Engineering (ACCE), Clinical

Engineering is the field of engineering that supports and advances patient care by applying engineering and management skills to healthcare technology (ACCE, 1992).

Biomedical Engineering sub-areas

Biomedical Engineering divides into four sub-areas:

1- Bioengineering focuses on pure research; for example, the study of the behaviour of neurons and cardiac cells with the aid of mathematical models and simulations;
2- Medical Engineering is directed to the research, design, and construction of instrumentation (mainly electronic), sensors, and prosthesis for the medical field;
3- Rehabilitation Engineering aims the development of electronic and mechanical systems for the improvement of the quality of life of physically challenged people.
4- Biomedical Engineering, also called Clinical or hospital engineering, focuses on certification and testing of medical devices; and hospital activities, such as design, adequacy, and execution of installations, consulting for the acquisition of devices, training of maintenance teams (Natarajan, 2010).

2.1.3 Clinical Engineering

Clinical engineering developed with a considerable early emphasis on the maintenance, electrical safety, and electronics aspects of medical equipment which encourages the consideration of broader safety aspects in healthcare.

Biomedical or Clinical engineer provides education for nursing, medical, and paramedical staff to facilitate their understanding of present technology and future trends. In consultation with medical and administrative staff, he or she must ensure that equipment purchases and hospital designs and systems are optimal and that technology acquisitions are appropriate; he or she must engage in applied research and development at all levels to improve patient care and make provisions for the safe and effective use of technology.

The clinical engineering department is responsible for efficiently managing all the technological resources, that related to medical equipment, which is 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. (Bronzino, 2000).

According to Davi, Judd and Zambuto (2004), clinical engineering department contribute to, and participate in, every phase of the equipment life cycle, from the capital budget planning, the equipment evaluation, and the performance validation, to the acceptance testing, user training, inventory control, repair and maintenance services, and incident investigation.

2.1.4 Functions of the Clinical Engineering Department

Bronzio and Hayes (1988) had stated that the primary activities of the clinical engineering department within the healthcare community to perform a wide variety of tasks in the modern hospital including the following:

1. Assisting hospital personnel to solve problems and help them fit together with medical devices.

2. Designing and supervising the structure and testing of superior purpose electronic equipment when commercially available devices cannot meet needs.

3. Conducting studies and research in contemporary design and construction methods as applied to medical and healthcare, such as the design of operating room suites, emergency room facilities.

4. Developing methods for calibrating and conducting performance checks on biomedical instrumentation; maintaining a set of fundamental electrical standards and instruments adequate for this work.

5. Providing informal instruction in electronic theory and practice to instrumentation section specialists and other medical centre electronics technicians for improved understanding of current developments.

6. Providing technical supervision for those aspects of a hospital electrical safety program that involves biomedical instrumentation.

7. Assisting service personnel in the diagnosis and solution of maintenance problems.

8. Developing and conducting instructional courses in medical device electronics for healthcare personnel.

9. Representing the hospital in dealings with outside organisations involving professional engineering responsibilities.

10. Serving as a consultant and adviser to research and clinical specialists and recommending solutions to instrumentation and electrical safety problems.

11. Safeguarding public safety by ensuring that the hospital follows recommended standards in all biomedical instrumentation use. (Bronzio and Hayes, 1988)

2.1.5 Responsibilities of the Clinical Engineering Department

According to Dolan (2009), the primary duties of the clinical engineering department are:

1- Education

a- Education of Biomedical engineering staff.

b- Education of healthcare facility staff.

2- Clinical Research/Development

a- Design of new equipment, patient aids, and techniques to aid in patient care.

b- Assistive devices.

3. Information Technology Applications

a- Development and management of hospital and patient information and physiological data acquisition systems.

b- Development and responsibility for patient care networks.

c- Integration of medical devices with IT networks.

4. Facility Planning

a- Advising and consulting with administrative and healthcare staff on matters related to the impact of technological developments in healthcare facility planning.

b- Standards and regulations.

5. Systems Management

a- Systems analysis

b- Design and evaluation of healthcare systems

c- Quality management

d- Risk management

6. Equipment Management

a- Planning-Functional program review

1- Technology planning

2- New equipment planning

3- Renewal equipment planning

b- Acquisition-Definition of clinical requirements

1- Survey of available equipment

2- Specification writing

3- Equipment evaluation

4- Generation of purchase documents

5- Vendor selection

6- Acceptance testing

c- Control-Inventory management

1- Maintenance

2- Repair

3- Test and calibration procedures

4- Scheduled inspection

5- Safety program

7. Patient Safety/Risk Management

a- Safety of medical equipment and systems in-patient care areas.

b- Risk management of systems, networks, and devices.

8. Regulatory Activities

1- Codes

2- National and international standards

3- Regulations and accreditations (Dolan, 2009)

2.1.6 Clinical Engineering External Factors

Dolan (2009) had whispered that with rapid changes in healthcare are occurring, other external factors would also affect the Biomedical engineering field:

1. Internationalisation of science and technology
2. Integration of Technology
3. Communications technology
4. Regulation of healthcare technology
5. Technology Management:
6. Standards and Regulatory Activities

2.1.7 Medical Devices Management

2.1.7.1 Introduction

It has been defined, management, as the art of getting things done through people in organisations. The French industrialist engineer Henri Fayol who had stated that as describes management (Hill and McShane, 2008) which contains from five primary functions: planning, organising, directing (or leading), coordinating, and controlling.

1- Planning is a formal process, when managers select goals, identify actions to attain those goals, allocate responsibility for implementing activities to specific individuals or units, measure the success of arrangements by comparing actual results against the goals, and revise plans accordingly. The most famous of planning approach is a strategy, which is an action that managers take to attain the purposes of animation.

2- Organising is the process of deciding who within an association will perform what tasks, where decisions will be completed, who reports to whom, and how different parts of the organisation will coordinate their activities to pursue a common goal.

3- Directing or Leading is the process of motivating, influencing, and directing others in the organisation to work productively in pursuit of organisational goals. Leading also entails articulating a grand strategic vision for the organisation and becoming a tireless advocate for that vision.

4- Coordinating is determining the timing and sequencing of activities so that they mesh properly, allocating the appropriate proportions of resources, times and priority, and adapting means to ends.

5- Controlling is the process of monitoring performance in contrast to goals, intervening when goals are not met and taking corrective action. (Hill and McShane, 2008). Health technology management (HTM) is a systematic process plan to manage health technology assets to achieve the core quality care at the best cost that begins with strategic planning as well as technology assessment and facilities planning, proceed with technology procurement, and conclude with service or maintenance management. (Judd,2000).

According to McCauley (2005), medical device management is funded by many methods. These include historical funding, funding based on the number and type of

devices, funding based on the number and type of beds and services in a healthcare organisation, or a combination of these and other factors such as various schemes.

Also, Judd T. (2005) realises that many countries have a shortage in the health technology resources that they need to improve their populations' health. As defined by the World Health Organisation (WHO), that funds include human resources, pharmaceuticals, equipment and supplies, and facilities.

Each country requires the development of an explicit policy, which is a rational process for identifying, acquiring, and managing needed resources in care delivery requires. The plan should address health technology use at all levels of a national healthcare system. The National Health Technology Policy concerns the best way to use available resources or to plan optimally for future needs that contains the following effects:

- Maximise limited financial investment in health.
- Minimise quality of waste.
- Maximise loans and donations.
- Ensure rational use of health resources.

2.1.7.3 Medical Devices Life cycle

According to Davi, Judd, and Zambuto (2004) a trend toward increased legislation in support of more regulations in healthcare to meet these requirements throughout the life cycle of the technology. If you subscribe to the saying, "You cannot manage what you do not measure, and you cannot measure what you do not define," then the need for the development of a systematic and comprehensive planning process for technology adoption is recognisable.

Most developing countries import medical devices. Thus, priority should be given to vendor and product registrations, user training and post-market surveillance of devices (correct use, problem alerts and recalls). Pre-market product control requires resources and expertise; governments could benefit from the work of primary medical device industrialised countries to assure regulatory compliance. International sharing of information on alert systems for medical devices is essential, as risk management is more effective with a large population database.

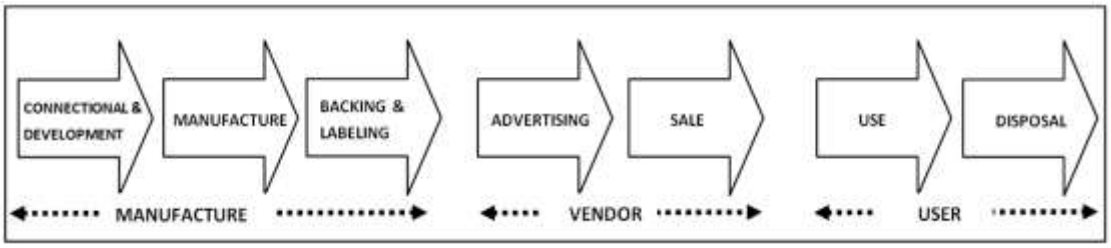


Figure 2.1: Medical devices Life cycle. (WHO, 2003)

The operational flowchart of medical devices life cycle management includes planning, evaluation, and initial purchase documentation requirements to ensure technical necessity fully supported. Introduction to the preventive maintenance program, unscheduled maintenance procedures, and retirement justification must be part of the process. Institutional-wide cooperation with the life cycle concept requires education and patience to convince healthcare providers of the team approach to managing medical equipment technology. This balanced approach requires communication and comprehensive planning by a healthcare team responsible for the evaluation of new and shared technology within the organisation. A medical technology evaluation committee (Figure 2.1), composed of representatives from administration, medical staff, nursing, safety department, biomedical engineering, and various services, can be a capable platform for the integration of technology and healthcare. (David and Judd, 2000).

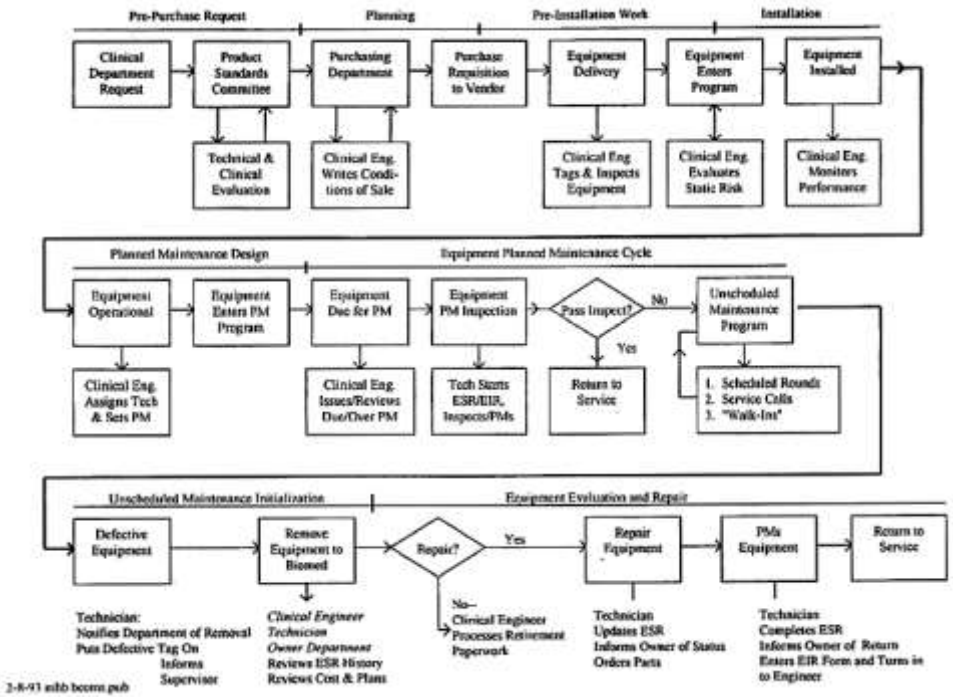


Figure 2.2: medical devices life cycle management. (Gullikson, 2000).

According to Davi, Judd, Zambuto (2004) acquisition of medical technology is accomplished primarily for five reasons:

1. To improve diagnostic, therapeutic, or rehabilitation efficiency.

2. To increase the health system's cost-effectiveness or reimbursement.

3. To reduce risk exposure and eliminate errors.

4. To attract high-quality professionals.

5. To expand the service area or to better serve the beneficiary base.

2.1.8 Medical Devices Planning

Medical devices planning is a process, of which the assessments of the attributes of a technology. It is distinguishable from technology management, which relates to the acquisition, application, utilisation, education, distribution, safety, maintenance, and repair of technologies once they are in place. Technology management is, in fact, a consequence of the technology planning process.

According to Davi, Judd and Zambuto (2004) adequately constructed medical technology management methodologies and tools provide objectives and guideline protocols for efficient practice and decision-making processes in the following stages in the technology life cycle:

1. Strategic technology planning
2. Technology assessment
3. Technology acquisition and implementation
4. Technology risk management and quality improvement
5. Technology utilisation and servicing
6. Technology value or cost/benefit ratio analysis

2.1.8.1 Strategic Technology Planning

According to Gary and Epstein (2005), the primary purpose of strategic technology planning is to gain a complete understanding of the existing technology-related equipment and services within the organisation and the expected progression of and

changes in services that can be forecast with an intent to provide a base on which to consider and time acquisition of future technology. Also, Davi, Judd, and Zambuto (2004), emphasise that strategic medical technology planning is essential for healthcare organisations to achieve their needs to (1) identify its goals; (2) select and define priorities;(3) allocate resources more efficiently; and (4) achieve system-wide integration.

Davi, Judd & Zambuto, (2004) suggest that strategic medical technology planning in healthcare organisations requires four steps: defining the needs to identify its goals; select and determine priorities; allocate resources more effectively and achieve system-wide integration. This strategic planning process contains five steps: 1- the scope of technology, 2- clinical necessity, 3- operational support, 4- market Preference, strategic planning process (Davi, Judd & Zambuto, 2004).

2.1.8.2 Medical Devices Assessment

Medical technology assessment (MTA) is a continuous process of evaluating the medical equipment in use, planning for future technology needs, and acquiring medical equipment (Cram, 2005). It is a significant function of a clinical engineering department to be well prepared for the challenge that begins with the assessment of the hospital's existing technology base. It requires a full understanding of the missions of the hospital, a familiarity with the healthcare delivery system, and the cooperation of the hospital administration and the medical staff. To maximise their effectiveness, clinical engineers need access to database services and libraries; the ability to visit scientific and clinical exhibits; the capability to establish an industrial network; and a relationship with peers throughout the country. The technology assessment process begins with a department or individual filling out a request for review form and a capital asset request for to be submitted to the hospital's product standards committee to determine where the assessment process to be initiated, and the priority for its completion. It also determines whether a previously established standard for this equipment already exists. Consider the following attributes: Accuracy and repeatability - Ease of use – Reliability - Expected user's skill level - Serviceability and warranty – Performance - Compatibility and interchangeability - Ability to be upgraded – Safety- Cost. (David, Judd, Zambuto, 2004)

According to Davi, Judd, and Zambuto (2004), technology assessment process contains six steps: 1- Technology Audit, 2- Budget Strategies, 3- Prerequisites for Medical Technology Assessment, 4 -Technology Assessment Program, 5- Technology Assessment, 6- Device Evaluation.

2.1.10 Technical Asset Management

According to Davi, Judd and Zambuto (2004) technical asset management and management provide a comprehensive and integrated approach to the analysis, implementation, and management of new or additional medical technology. The attributes of ideal asset management are demonstrated through the continuous availability of robust and reliable equipment and systems at the lowest possible life cycle cost, whenever and wherever needed. Asset management attributes are:

1. Acquisition and equipment life cycle
2. Technical support
3. Information and Training
4. Monitoring and evaluation
5. Documentation.

2.2 Medical Devices Maintenance

2.2.1 Overview

Medical devices maintenance not only costs billions of dollars every year from the limited national income, but also if they are not handled professionally, thus creating a significant health risk to medical workers, the patients, and the environment. In this case, a comprehensive effort to understand how medical devices managed by hospitals, clinics, and other healthcare facilities is needed. Because, medical technology is an integral component of the healthcare delivery system, high efforts to improve patient safety and the quality of healthcare delivery that must consider the omnipresence of medical technology. (AAMI, 2000).

According to Baretich (2005) the key objectives of a scheduled maintenance program for medical equipment to reduce the risk of injury or adverse impact on patient care, to decrease equipment life cycle costs, and to comply with codes, standards, and regulations.

All devices carry a certain degree of risk and could cause problems in specific circumstances. Many medical devices problems cannot be detected until extensive market experience is gained. For example, an implantable device may fail in a manner that was not predictable at the time of implantation; the failure may reflect conditions unique to specific patients. For other devices, component failure can also be unpredictable or random. The current approach to device safety is to estimate the potential of a device is becoming a hazard that could result in safety problems and may cause harm. (WHO, 2003).

According to Baretich (2005) the essential components of a scheduled maintenance program are the following:

1- Inventory: Definition of medical devices to be included in the program.
2- Procedures: Definition of maintenance activities to be performed on devices in the program inventory.
3- Scheduling: Definition of when maintenance activities are to be performed on devices in the program inventory.
4- Monitoring: Continuous measurement and periodic review of program performance.

McCauley (2005) designates maintenance and repair activity is required to ensure that devices are kept functioning within limits imposed by the test criteria and to return devices to the necessary level of operating after breakage or another failure.

2.2.2 Medical Devices Maintenance Main Factors

According to McCauley (2005), several factors affect medical devices maintenance, such as:

1- Regulation
2- Risk Management
3- Maintenance Strategies:
4- Maintenance Planning
5- Fault Diagnosis
6- Testing
7- Computerised Maintenance and Management System
8- Outsourcing
9- Clinical Engineering Program Indicators

10- Personnel management:
11- Quality
12- Safety
13- Training

In the following pages is a short explanation for each of these factors:

1- Regulation

McCauley (2005) emphases that before maintenance and repair work is carried out, it is essential to establish the regulatory framework under which such a job is to be undertaken, to ensure compliance with local requirements. Requirements vary according to location, the type of equipment being managed, the nature of the healthcare organisation's operation, and possibly among different manufacturers. In some countries, there is little regulation, and work might be carried out by any capable person, regardless of qualifications, experience, or training. To some extent this situation exists almost everywhere, as some organisations employ (or contract out to) repair personnel who have had limited training, opting instead to provide skilled supervision so that people who have minimal qualifications can do the job. Also, various standards govern medical device management, and most countries adopt at least one such measure, either as part of the overall quality process or more rigorously as a legislative requirement. The rules define the nature and frequency of safety and performance testing.

2- Risk Management

McCauley (2005) stresses that many medical device management programs are relatively under-resourced, particularly with the adoption of more complex technology that presents a difficult situation. The scarce resources are allocated to yearly safety and performance testing, for mandatory or accreditation reasons, and then the repair accumulation may increase to a level where clinical service delivery becomes affected.

3- Maintenance Strategies

McCauley (2005) describes significant maintenance and calibration strategies are essential factors to improve device management efficiency over time. They bring increases in productivity to reduce the overall risk.

4- Maintenance Planning

McCauley (2005) describes the planning of maintenance procedures is significant. This process requires detailed knowledge of maintenance requirements and the resources that are necessary to perform maintenance. The resources necessary include labour, parts, materials, and tool costs. Also, Good maintenance planning helps to focus on major generic maintenance requirements that track any increases in efficiency to improve the availability of resources, allowing smaller or difficult issues to be attempted.

5- Fault Diagnosis

Accurate fault diagnosis is critical because the cause of faults is not readily apparent that leaves repair personnel is trusting in their skills and experience to identify the cause accurately. (McCauley, 2005).

6- Testing

After any maintenance procedure or repair, testing is required to ensure that the device is safe and performing up to specifications. Whether a full safety and performance test should be run is a matter for professional judgment, dependent on the level of repair. (McCauley, 2005).

7- Computerised Maintenance and Management System

Campbell (2005) describes the Computerised Maintenance and Management System as the foundation of the successful clinical engineering program is the computerised maintenance and management system (CMMS). This database will house the information that the clinical engineering staff will use to make informed decisions and recommendations relating to equipment management. Careful selection of a computerised maintenance and management system will permit access to this information using a variety of queries and the ability to format the data in a useful manner. The CMMS also has evolved into a critical process tool for organising the work of the department. While some clinical engineering department develops their CMMS, there is a variety of products available on the market. Some of these products are designed specifically for clinical engineering and interface with standard test equipment; others are more specific. The selected CMMS should permit keeping an

equipment inventory with a variety of information including a unique Numeric identifier, manufacturer, model number, and serial number, and it should have the capability to generate work orders on a scheduled basis and demand. Other attractive features include the ability to track a parts inventory and parts utilisation, financial tracking capability, and payroll functions. These various features are arranged in modules that interact with one another. A high degree of integration between modules is a desirable feature of a CMMS. For example, some systems contain a module for the definition of device-specific preventive maintenance procedures that can be married to devices in the inventory module. When a scheduled preventive maintenance work order for that specific device is generated, the appropriate preventive maintenance procedure appears in the work order module screen. Access to the CMMS by the clinical engineering staff is desirable wherever work with equipment is performed. Therefore, transportability of the CMMS into the clinical care environment is also a helpful feature. This can be accomplished through a connection to the hospital's backbone—wireless communications—or through upload/download of the database (or some portion) onto portable devices. (Campbell, 2005)

8- Outsourcing

Smithson and Dickey (2005) describe Outsourcing as the transfer of any defined business operation or responsibility to another organisation. In clinical engineering, the handover of responsibility for selected portions of equipment service, procurement, or program management to an external business entity or organisation, all for one agreed upon or "not to exceed" price. It could involve the transfer of the financial risk, with or without service staffing, as well. The company providing the outsourced service makes all service decisions and assumes responsibility for all outcomes (i.e., good and bad).

9- Clinical Engineering Indicators

Autio (2005) emphasises that as new business practices were integrated into existing clinical engineering programs, it became essential to develop objective, reliable indicators to document performance and to measure improvements in the services provided. The indicator is a reliable, valid, quantitative process or outcome measurement that relates to performance quality. This objective measurement is reliable if different people can derive the same measure from the same data set. It is valid if the information obtained from the analysis presents an opportunity for quality

improvement. An indicator can be positive (e.g., the number of IPMs completed in a month) or negative (e.g., the number of IPMs not completed in a month). In either case, it provides information for further analysis. An indicator can assess different aspects of performance, including timeliness, efficiency, productivity, efficacy, safety, or customer satisfaction. The reliability and validity of program indicators evolve to the highest level possible. (Autio, 2005).

10- Personnel Management

Wear (2005) emphasise that personnel management is an essential role of a clinical engineering department. Personnel management can comprise a significant portion of the director's job. The hospital needs to establish an appropriate staffing level and to monitor this staffing level. Appropriate job descriptions must be written and modified as the technology of the hospital equipment that is being maintained changes. The recruitment of staff is a function of the director. Having a good retention program so that there are no vacancies to fill over a period can reduce this part of the job. Supervision of the staff is an essential function to ensure that the engineers and technicians are motivated to provide excellent customer service and maximum productivity. A fair evaluation of the individuals, including their customer service and productivity, is an essential aspect of the retention. At the same time, there must be appropriate compensation. A critical part of any clinical engineering program is that there is some pathway for career development and a career ladder that employees can climb. Without a career ladder, it is more difficult to retain employees because they will seek promotions and more challenging job opportunities elsewhere. Where technicians and engineers may belong to a union, the director must maintain appropriate management-labour relations. (Wear, 2005).

11- Quality

Judd, T. (2005) emphasises that clinical engineers need to understand and to apply basic quality principles in their work, such as having the right people doing the right thing at the right time, and they need to learn how their health technology planning and management work can best contribute to improved quality of care. Techniques are presented for improving the quality of healthcare delivery and technology management practice.

Quality can be measured and improved through:

1- Appropriate quality culture and quality improvement infrastructure

2- Prioritized quality improvement initiatives based on impact (disease burden), improvability (quantified gap between current and evidence-based best practice), and inclusiveness (broad relevance and reach)

3- Appropriate quality improvement indicators and tools

4- Performance feedback and other methods

5- Using the best science for care (evidence-based medicine) and clinical engineering practices

12- Safety

As device-related mini systems increase in number, the hazards associated with their use become more varied, and the clinical environment, more complicated. Devices can become non-functional because of electromagnetic interference (EMI), or they can become fire-ignition sources for patients who are undergoing treatment in oxygen-enriched environments. Such medical device-related events require a clinical engineering investigation of the incident and recommendations to prevent similar, future events. Because corrective recommendations frequently involve hospital professional staff and processes, they must be integrated into the total hospital safety program. (Shepherd, 2005)

Also, Shepherd (2005) highlighted that medical devices should do what the healthcare practitioner wants them to do (effectiveness) and not do what the practitioner does not want them to do (safety). These are the two sides of the coin of clinical engineering. This chapter looks at the safety side of the coin. However, hospital safety programs—designed to protect patients, visitors, and staff—are practical applications of the medical dictum “First, not harm.” They are fundamental in creating an environment in which effective patient care can occur. Since its earliest days, the profession of clinical engineering has addressed safety in the clinical setting. Clinical engineering can extend their excellent record of contributions to hospital safety by working in cooperation with professional colleagues throughout the healthcare delivery system, (Baretich, 2005)

13- Training

Campbell (2005) emphasises the necessity of training because of the tight labour market; the best job candidates will likely not be the perfect candidates. Therefore, the new employee's orientation and training program have become more critical than ever.

Additionally, provision of training has become an important staff-retention tool. Training can be negotiated into new equipment purchases to minimise the associated expense. It also can be obtained at cost from original equipment manufacturers or independent training centres. Technical training seminars are offered in conjunction with professional society meetings. Service manuals must be obtained for the training to be beneficial. Teleconferences and Internet-based training provide a cost-effective methodology for training on specific topics. (Campbell, 2005)

2.2.3 Medical Devices Failures

According to the World Health Organisation, the absence of preventive maintenance, inability to repair excessive causes equipment downtime from 25–35% of equipment out of service. These failures are the responsibilities of many people. Medical Devices Failures occurs due to five reasons: 1- device: Design -Manufacturer- Maintenance, 2- Medical Devices Failures due to users: Misuse, Abuse use, Inattention, 3- Medical Devices Failures due to Facility, Human Factors Design - Deterioration - Part/Systems Design – Maintainer, 4- Medical Devices Failures due to Environment, and 5- Medical Devices Failures due to Patient. (Dyro, 2005).

2.2.4 Medical Device Troubleshooting

Dyro and Morris (2005) describe the goal of troubleshooting is to repair or correct a fault in an instrument system.

An instrument system consists of three major components: The operator, the environment, and the instrument.

A failure in, or poor performance of, an instrument system can be the result of difficulties in any one of the system's three major components.

1. The operator: The end-user typically makes the initial decision that a failure or malfunction has occurred difficulties can be due to such factors as incorrect or improper operation, or incorrectly set controls.
2. The environment: The total environment surrounding the instrument and operator problems can be related to environmental and other factors such as temperature, drafts, dirt, vibration, incorrect electrical supply, electrical or chemical interference, and input exceeding the dynamic range, wrong reagents, or bad electrodes.
3. The instrument: The device that performs a task such as a measurement or control.

Failures of the device fall into two general categories: (1) non-electric (e.g., lose or broken connections, dirt, corrosion, or mechanical wear. These are the most probable sources of instrument failures); and (2) electronic (a component or circuit failure). In general, the electronic portion of an instrument is the most reliable part.). The first problem of troubleshooting is to determine whether the fault is in operation, environment, or instrument component of the instrument system. The purpose of the methodology of troubleshooting is to gather information about the poor performance or failure of an instrument system logically and systematically. (Dyro and Morris, 2005)

The troubleshooter must be thoroughly familiar with the basic principles of measurements and with the test equipment to be used before the maximum information can be obtained from any analysis performed. One must know what, where, when, how, and why to measure, and must be able to interpret the results of a study. Troubleshooting can require a wide range of tools from the primary human senses (eyes ears, nose, mouth, and hands) to specialised equipment such as ventilator analysers. (Dyro and Morris, 2005)

No measurement should be made without knowing, before the measure, what to expect because of the analysis. If you do not know what voltage or signal you should have at a point in a circuit, how can you tell whether the results of the measurement are correct or incorrect? The purpose of using test equipment and making measurements while troubleshooting is to gain information about failure or fault, or about the cause of a failure or error. (Dyro and Morris, 2005)

2.3 Medical Devises Maintenance in Saudi Arabia

2.3.1 Healthcare in Saudi Arabia

The Kingdom's guiding principle on health merely is expressed that the provision of free health services for the benefit of all the citizens of Saudi Arabia. The Ministry of Health policy reflects the Government's national development strategy, which is committed to improving the quality of life of the Saudi people, and to help them to participate fully in the development plan and to benefit from it. To carry out this policy, the Ministry of Health provides a whole range of health services (preventive, corrective, educational and rehabilitative) to the entire population. This goal can be achieved through a network of hospitals and primary healthcare centres which are distributed throughout the country. Saudi Arabian General Investment Authority (SAGIA) had expected the investment in medical device manufacturing in Saudi Arabia in 2015 about one million US dollars from multinational medical device manufacturers in local manufacturing capabilities, to develop an advanced medical device manufacturing cluster, thereby laying the foundation for home-grown Saudi Arabian manufacturing businesses for the Saudi Arabian. (SAGIA, 2015)

In Saudi Arabia, several organisations involve providing healthcare services such as:

- Ministry of Health (MOH)
- Other Governmental Hospitals
- Saudi Red Crescent Authority
- Saudi Commission for Health Specialties (SCHS)
- Saudi Food and Drug Authority (SFDA)
- Council of Cooperative Health Insurance
- Saudi Health Council
- Public and private universities and colleges.
- Private Hospitals

Another essential factor affects health care services in Saudi Arabia is the new strategic plan for the country which called "Vision 2030" that focuses on three themes: a vibrant society, a thriving economy and an ambitious nation. This first theme is vital to achieving the Vision and a strong foundation for economic prosperity. It is essential for a vibrant society. Members of this society live by the Islamic principle of moderation,

are proud of their national identity and their ancient cultural heritage, enjoy a good life in a beautiful environment, are protected by caring families and are supported by an empowering social and health care system. In the second theme, a thriving economy provides opportunities for all by building an education system aligned with market needs and creating economic opportunities for the entrepreneur, the small enterprise as well as the large corporation. Therefore, it will develop investment tools to unlock the promising economic sectors, diversify the economy and create job opportunities. It will also grow the economy and improve the quality of the services, by privatising some government services, improving the business environment, attracting the most excellent talent and the best investments globally, and leveraging the unique strategic location in connecting three continents. The third theme is built on a practical, transparent, accountable, enabling and high-performing government. This will also prepare the right environment for the citizens, private sector and non-profit sector to take their responsibilities and take the initiative in facing challenges and seizing opportunities. In each of these themes, highlighted a selection of commitments and goals, as a reflection of its ambition and a representation of what it aims to achieve. This Vision will be the point of reference for future decisions so that all future projects are aligned to their content. So, the vision will achieve its goals by apply efficiency and responsibility at all levels which give this study a significant value. (Council of Economic and Development Affairs, 2016).

To meet the increased demand for healthcare, the government's annual expenditure on the health sector in 2015 was estimated at 160 billion Saudi Riyals (42.7 US$ billions) about 18% from the total budget 860 billion Saudi Riyals (229.3 US$ billions). The MOH has allocated over SR 7 billion (approximately US$ 2 billions) for 67 health projects throughout the country as part of its fiscal 2012. The projects include the establishment of 12 new hospitals with a combined bed capacity of 3,100 beds, as well as some comprehensive medical clinics, oncology centres, and specialised dental centres. (MOH, 2015)

Ministry of Health has finalised plans to establish new hospitals, renovate, and expand existing hospitals. The growing scope of health care services needed in Saudi Arabia had increased last decades to meet the needs of all aspects of healthcare essentials, including all hospitals and healthcare centres included the development of a skilled healthcare workforce, as well as the control of the diseases and epidemics that were prevalent during that time nationwide.

The healthcare facts in Saudi Arabia

Table 2.1: The healthcare facts in Saudi Arabia. (Sourer: Ministry of Health, 2017)

Total Estimated Population in Saudi Arabia is in 2013	30,000,000
Annual population growth rate	2.7 %
Percentage of population under 15 years	30.8 %
Percentage of population 15- 64 years	66.2 %
Life expectancy at birth	75 year
Gross Domestic Product (GDP) per capita	24,914 in USD
Percentage of MOH Budget of total governmental budget	6.6 %
Total primary care centres nationwide	2361
Total Hospitals nationwide	487
Total Hospitals belongs to MOH	282
Other Governmental Hospitals	47
Private Hospitals	158
Hospital Beds	72981 Beds

To fulfil its mission of promoting optimal quality and safety of healthcare facilities in the Kingdom, the Saudi Central Board for Accreditation of Healthcare Institutions is issuing qualification standards for companies who operate healthcare facilities. Because the level of professionalism and efficiency of the companies that run healthcare facilities directly reflects the level of quality and safety measures afforded their patients, Saudi Central Board of Accreditation for Healthcare Institutions (CBAHI) has developed a set of qualifications to differentiate between these companies. CBAHI committees have established standards for the classification of private hospitals in the Kingdom to assist the Ministry of Health and the Council of Cooperative Health Insurance in developing fair pricing for healthcare services provided by private hospitals. CBAHI has also mandated that specific necessary medical equipment be available in all healthcare facilities, regardless of facility type or scope of work to ensure quality, safe service for patients. (CBAHI, 2015). CBAHI had established to improve healthcare quality standards in the Kingdom and to implement and accredit the medical quality standards and patient safety by national origin working systems, universal implementation, and distinguished efficiency. There are 96 hospitals accredited nationwide; 32 are government hospitals and 54 private hospitals. (MOH, 2018). CBAHI had established hospital standards accreditation program as a self-assessment and external peer review process against stated peer-set standards. The accreditation survey is a formal process by which a recognised body assesses and acknowledges that a healthcare organisation meets applicable predetermined and published standards. A standard is a statement of excellence, developed by peers against which conformity of the healthcare organisation is evaluated. (CBAHI, 2011).

The CBAHI Hospitals Standards are assembled into (22) chapters around critical services and functions common to hospitals: 1. Leadership 2. Medical Staff and Provision of Care 3. Nursing 4. Quality Management and Patient Safety 5. Patient & Family Education and Rights 6. Anaesthesia 7. Intensive Care Unit: Adult, Paediatric, Coronary Care Unit, Neonate. 8. Operating Room 9. Labour & Delivery 10. Haemodialysis 11. Emergency Room 12. Radiology 13. Burn Care 14. Medical & Radiation Oncology 15. Psychiatry 16. Specialised Areas: Respiratory Services, Dietary Service, Social Workers & Rehabilitation Service. 17. Ambulatory Care Services. 18. Management of Information and Medical Records. 19. Infection Control 20. Pharmacy 21. Laboratory 22. Facility Management and Safety. (CBAHI, 2011).

Each chapter has an introduction which explains the chapter's relevance and contribution to safety and high-quality patient care. Each standard has a statement and when required sub-standards are developed to clarify further requirements. Additionally, every standard has evidence(s) of compliance (EC) that is going to be scored during the survey. The statement on the right side of each EC is called Primary Source of Information (PSOI). It defines the primary method and source of information that is usually used to assess compliance with EC during the survey. However, in certain circumstances, the surveyor may elect to use other PSOI. (CBAHI, 2011).

2.3.2 Medical Devises Maintenance in Saudi Arabia

Biomedical Engineering was introduced in the healthcare environment a long time ago in Saudi Arabia. It goes back to more than four decades where most of the healthcare providers were government facilities. They adapted assigned the medical equipment companies who care for their products within the healthcare facilities. There were some complications in this process, as the healthcare facilities must obey the companies' terms, conditions, and roles, which cost the facilities much money. In the last three decades, the developments in the field of medical equipment were speedy, and the number of healthcare providers increased very rapidly including private businesses.

Biomedical engineering technology has affected every aspect of our lives. It has mainly reshaped medical care in the last three decades, and engineering professionals have become intrinsically involved in many efforts. Clinical engineering departments in Saudi Arabia have emerged with a general objective of assisting in the struggle against disease and disability by providing tools and techniques for research, diagnosis, and

treatment. Most of the medical devices maintenance services in the Kingdom run on a contract basis, and employees change frequently. Thus, it is difficult to find the same experienced trainers all the time. Some of the healthcare facilities have their own maintenance teams. Clinical/Biomedical engineering department is one of these maintenance teams who care for all medical equipment within the facility. Almost all the maintenance staff are foreigners (or non-Saudis). The problem started when the healthcare facilities demand Saudization of such technical job positions. The Biomedical equipment technicians are one of those positions that required to be fulfilled.

To ensure high-quality healthcare services and patient safety, the Saudi Central Board for Accreditation of Healthcare Facilities, had established a list of required medical equipment that must be available in any healthcare facility of any type before commencing operations in the Kingdom. Creating this medical equipment prerequisite list demonstrates the Saudi Central Board's belief that the efficiency of healthcare facilities relies heavily on their equipment and that it reflects the level and quality of their services. CBAHI underwent careful consideration while preparing the list of prerequisite medical equipment and knowledge that it would be made mandatory for all healthcare facilities, independent or affiliated, existing or planned. The aim has been to ensure that healthcare services provided by any facility in the Kingdom are safe and efficient, as outlined in the standards. (CBAHI, 2015).

2.3.3 Clinical Engineering Departments in Saudi Arabian Hospitals

According to a field study, (Albadr, 2006), Clinical engineering departments in Saudi Arabian hospitals activities divided into ten main events as follows:

Table 2.2: CEDs activities in Saudi Arabian hospitals

Department activities	Average (%)
1. Equipment Inventory	5.6
2. Preventive Maintenance (PM)	30.4
3. Corrective Maintenance (CM)	31.5
4. Pre-purchase Consultation:	9.4
5. Acceptance Testing (Incoming Inspections)	6.4
6. Management of Service Contracts	4.6
7. Risk Management	2.5
8. Quality Control	3.3
9. Education and Training	5.2
10. Research and Development	1.4
Total	100%

From the previous table, it was evident that Preventive Maintenance (PM) and Corrective Maintenance (CM) take most of the CE personnel time which is more than 60%. In the same time, other activities that related to testing and calibration such as Acceptance Testing (Incoming Inspections) (6.4 %) and Quality Control (3.3 %) have very low in time (less than 10%). Thus, it will give more details in the next section.

2.3.4 Medical Devices Maintenance Regulations in Saudi Arabia

In Saudi Arabia, as part of the efforts of the Saudi Central Board for Accreditation of Healthcare Facilities to ensure high-quality healthcare services and patient safety, they have established a list of required medical equipment that must be available in any healthcare facility of any type before commencing operations in the Kingdom. Creating this medical equipment prerequisite list demonstrates the Saudi Central Board's belief that the efficiency of healthcare facilities relies heavily on their equipment and that it reflects the level and quality of their services. CBAHI underwent careful consideration while preparing the list of prerequisite medical equipment, understanding that it would be made mandatory for all healthcare facilities, big or small, independent or affiliated, existing or planned. The aim has been to ensure that healthcare services provided by any facility in the Kingdom are safe and efficient, as outlined in the standards. CBAHI standards require from each organisation to ensure that staff are educated in the safe operation of equipment, with Evidence of Compliance (EC) of staff education on the safe operation of equipment together with tools to ensure competency of staff. (CBAHI, 2015).

In CBAHI standard for Safety and Management Program (FMS.1) requires from the hospital administration to supports and establishes a safety management program that covers seven critical plans:(Safety of the Building - Security - Hazardous materials and waste disposals - Externals and Emergency - Internal Emergency - External Emergency - Fire Safety - Medical Equipment - Utility System).

According to CBAHI standards (2011) The Medical Equipment plan should cover the following and are implemented as appropriate:

1- An inventory of all hospital equipment and their location.
2- The active Preventive Maintenance (PM) as per the manufacturer recommendations (at least 95% receive PM) that includes electrical safety testing for

patient related equipment, each piece of equipment has a checklist for its maintenance schedule, failure incidence, repairs don, and there is a written policy to perform inspection on all new equipment before putting into operation.

3- Availability of Safety manuals at biomedical engineering workshops and Operator manual for each equipment at each dept./section using the equipment.

4- A written policy for medical tagging equipment as PM with testing date and due date, Inventory number, Removal from service, Safety check

5- A written policy on removal of equipment from service.

6- The hospital staff, physicians, and nurses, and paramedics are trained to operate the medical equipment assigned to them and the hazards attached to it; training includes new equipment, staff transferred from section to another, new personnel hired, and reoccurrence misuse of equipment.

7- Occurrence Variance Reports (OVRs) are used to report medical equipment related incidents, and corrective actions are taken.

8- There is statistical Preventative Maintenance (PM) data for upgrading/ replacing of equipment.

9- Written policies to cover agent/ sub-contractor repair, eliminate the use of extension cords, restrict the use of cellular phones in the following critical area (ICU, OR, Cardiology). (CBAHI, 2011)

2.3.5 Medical Devises Maintenance Standards in Saudi Arabia

CBAHI standards (2011) encourages hospitals to maintain medical devices in good condition. This may include in the medical equipment plan to cover the following and are implemented as appropriate:

1. The active preventive maintenance (PM) as per the manufacturer recommendations (at least 95% receive PM) that includes electrical safety testing for patient related equipment, each piece of equipment has a checklist for its maintenance schedule, failure incidence, repairs don,

2. A written policy to perform an inspection of all new equipment before putting into operation.

3. A written policy for tagging medical equipment as PM with testing date and due date,

4. There is statistical Preventative Maintenance (PM) data for upgrading/ replacing of equipment.

5. Written policies to cover agent/ sub-contractor repair, eliminate the use of extension cords, restrict the use of cellular phones in the following critical area) Intensive Care Uni (ICU), operating room (OR), Cardiology). (CBAHI, 2011).

Also, CBAHI standards had emphases such certain critical medical devices, for example:

1. The Radiation Oncology unit has a written safety plan which includes periodic inspection, maintenance, and calibration of the linear accelerator and other radiation equipment.
2. Regular calibration of respiratory equipment.
3. The lab has a documented procedure defining how pipets are checked for accuracy of calibration using certified balance, and this includes pipets are checked for accuracy before being placed in service initially, and results are documented, pipets are checked every six months, and results are documented, and pipets are checked for reproducibility and the results are recorded. (CBAHI, 2011).

From the other side, SFDA requires to take all appropriate measures to ensure that medical devices authorized by the SFDA to be placed on the market in the KSA are subject to post-marketing surveillance and comply with the requirements of the regulation to monitor the safe use of medical devices within the KSA by encouraging medical device users and patients to notify any adverse events of which they become aware. Also, The SFDA shall implement the appropriate market control policy and associated procedures, intended to monitor medical devices placed on the KSA market and to ensure, in cases of non-compliance, that necessary actions to enforce conformity are taken. The procedures also specify the responsibilities of the organisations involved in the importation and distribution activities regarding their market control activities and responsibilities. The SFDA shall review the functioning of its market control activities periodically and take appropriate measures to increase their effectiveness, where necessary. (SFDA, 2011).

2.3.6 Challenges of Medical Devices Maintenance in Saudi Arabia

1. There are no such implemented regulations that applied to make sure that each hospital has its policy to maintain its equipment.
2. With very rapid failure causes, it is necessary to establish a central national monitoring canter for medical devices maintenance.
3. Once, there is no full quality assurance program applied in each hospital; it is widespread to have a variance between the actual data with reported one.
4. Without having the test equipment calibrated, there is no guarantee to ensure that uniform standards are met
5. Maintaining the test equipment is very expensive to be sent abroad, so that some hospital may delay the calibration process.
6. Without having such a national calibration canter, it is hard to make sure that all the medical devices are safe. (Albadr, 2015).

2.3.7 Clinical Engineering Program Indicators

Autio (2005) emphasise that as new business practices were integrated into existing clinical engineering programs, it became essential to develop objective, reliable indicators to document performance and to measure improvements in the services provided. The indicator is a constant, valid, quantitative process or outcome measurement that relates to performance quality. This objective measurement is reliable if different people can derive the same measure from the same data set. It is valid if the information obtained from the analysis presents an opportunity for quality improvement. An indicator can be positive (e.g., the numbers of Inspection and preventive maintenance IPMs completed in a month) or negative (not completed in a month). In either case, it provides information for further analysis. An indicator can assess different aspects of performance, including timeliness, efficiency, productivity, efficacy, safety, and customer satisfaction. The reliability and validity of program indicators evolve to the highest level possible. (Autio, 2005).

2.3.7.1 Performance Indicators

The designing of a performance of the program indicators that uses program indicators to manage clinical engineering performance requires careful attention to detail and

must be integrated with the overall program goals. Autio, (2005) suggests indicator management process in 8 steps:

1- Identify the Indicator and the Threshold

A specific part of the program to monitor performance should be selected carefully. This selection process may result from a professional assessment of the program, user-satisfaction surveys choices made staff members, suggestions from the administration, and identification of a quality improvement opportunity or benchmarking with another organisation. One should identify the specific part of the program being monitored, describe any specific terminology used, and define the indicator to be used to control performance.

2- Gather Indicator Data

Gather Indicator Data: Once an indicator is determined, the various data sources and data elements must be identified. A standardised database assists significantly in this process because the staff continues to use the same method as before to collect data. Timeliness of data collection is essential. Staff should be encouraged to document these activities promptly to allow for rapid data collection.

3- Evaluate Indicator Data

Evaluate Indicator Data: as data are gathered, it is in a manner that is easy to interpret. Using thresholds often allows the use of a single number to define performance. This can be quickly reported in tabular or graphical format.

4- Determine if limit Exceeded or not?

Determine Threshold: One first should determine whether the threshold of the indicator data was met. If so, then one should proceed to the next step of looking for trends and patterns. If the threshold was not met, then a quality improvement opportunity possibly exists and must be explored. This requires a more detailed analysis of the indicator data. Sometimes a department decides to change the threshold measurement based on historical information and a desire to better document the performance provided by a department.

5- Trend or Pattern Identified

Identify Trends or Patterns: A trend is a general direction that an indicator takes over a period. It can be positive, negative, or neutral. A pattern is a distribution of indicator measurements. A pattern analysis often takes place after a threshold is crossed or a trend is identified. Additional information is often required to answer questions that may arise, to identify trends or patterns. Again, proactive staff participation is vital during this process.

6- Identify Quality Improvement Opportunity

Identify Quality Improvement Opportunity: During this time, one should carefully review the data with the staff to determine the reasons why the threshold was not met or to identify trends or patterns. This is an important process that must be approached proactively. One must carefully look at the process to determine problems. Difficult questions often must be asked. Were enough resources allocated to perform this service within the timeframe required? Was appropriate priority given to providing this service within the timeframe identified? When obstacles are identified, options for removing them must be considered. Careful review with staff will identify opportunities that can improve the current process. These improvements must be determined, and then an action plan must be developed to implement them. An action plan identifies the problem, the data that were assessed, the analysis of the data, and recommended actions to be taken. This documentation is an essential part of this process. It starts to tell the story of what the department is doing, what was found, and the way to plan to improve it. A critical step in this process is to review this action plan to document whether the solution was successful in improving performance. This can be accomplished by using the same indicators to monitor performance after the action plan was implemented. This is an iterative process, continually undergoing improvement.

7- Modify Indicator

Modify Indicator: When a quality improvement opportunity is identified, the indicator often will evolve. This is the time to redefine the indicator and the threshold, and then begin the process again. At some point, one may decide that there is no longer the need to manage this indicator as intensively as in the past. At this point, the indicator

may be retired, or it may be used to report performance. The only time when one would take any further action is if a threshold is crossed. (Autio, 2005).

2.4 Decision Support System

2.4.1 Overview

In this section, an overview of decision support systems, then an explanation of the different terminologies that use in decision support systems, after that, there is a description of how expert systems work and finally, there is a description of some applications of expert and decision support systems especially in maintenance.

According to Cheng and Dyro (2005), proper management has an impact on the maintenance function that needs to be met before the acquisition of the device to aid the following decision-making process:

1. Demonstrated needs and benefits
2. Available qualified users
3. Approved and reassured source of recurrent operating budget
4. Confirmed maintenance services and support
5. Adequate environment support
6. Regulatory compliance

If these conditions are met, problems (including maintenance) that can occur later will be reduced, and potential problems can be anticipated rather than coming as surprises that cause wastes of precious resources as well as evident frustration for the maintainer. (Cheng and Dyro, 2005).

A background analysis and requirement specification of a support system for decision making should take into consideration factors, such as : type of decision problem (policy, operations, resource allocation, etc.), domain and scope of the decision problem, organisational and structural boundaries, decision-making process, organisational and structural boundaries, decision-making process, impact on and synergy with the existing system, expected consequences of decision execution, profiles of decision-makers (users of the system), external constraints and contexts, and objectives of a DSS. (Kersten, Mikolajuk, and Yeh, 2000)

2.4.2 Decision Support Systems Definition

Decision support systems (DSS) are computer-based systems used to assist and aid decision makers in their decision-making processes. (Kersten, Mikolajuk, and Yeh, 2000). Also, the Decision support system is an interactive computer-based system designed to help a person or a group of people to make decisions in a specific domain, while the expert system is a computer program capable of performing at the level of a human expert in a narrow field. Decision support systems had related of some computer aspects such as computer intelligence, rule-based expert systems, fuzzy expert systems, frame-based expert systems, artificial neural networks, evolutionary computation, hybrid intelligent systems and knowledge engineering. Expert systems have five primary components: the knowledge base, the database، the inference engine, the explanation facilities and the user interface. (Negnevitsky, 2005)

2.4.3 Decision Support Systems structure

The Decision support system (DSS) has a structure containing data components and software components. The data components include data, models and solution databases. It also requires a bank with dialogue primitives that are used to compose interfaces. The software components comprise a database management system (DBMS) capable of handling the databases, a model base management system (MBMS) to handle the model base and a solution (scenario) management system. DBMS and MBMS need a broad array of data management and representation functions to manipulate the different databases as well as the model base. The solution management component needs several functions to generate and evaluate decision alternatives and scenarios. The dialogue system controls the display of information and the system's interaction with the user. (Kersten, Mikolajuk, and Yeh, 2000).

2.4.4 Decision Support Systems Applications in Clinical Engineering

Seaman (2005) describes using the decision-making approach as an essential part of the management process by the development of modelling skills. A model is an abstraction of a real-world means, such as transport-delivery system, customer service, or behaviour of healthcare markets. Sound analysis of a model’s output can help to improve an organisation, service, or program’s performance. For such models

to be beneficial, their results must be communicated to the organisation. To identify the problem and to utilise the information that the models generate, the ability to ask the right questions and good acumen in listening and communication skills are necessary.

In advance to solve organisational, production, and related problems most efficiently, clinical engineers need to study the medical devices management process carefully and its requirements, design logistics and information systems, and use mathematical analysis methods to meet those requirements. By developing a management control system is essential to aid in financial planning and cost analysis, process planning and control systems to coordinate activities and to control the services, quality, and design or improve systems for the physical distribution of materials and services.

Clinical engineers conduct surveys to find facility locations with the best combination of resources, transportation, accessibility, and costs. They also develop wage-and-salary administration systems and job evaluation programs. (Seaman, 2005)

2.4.5 Decision Analysis

A Decision analysis a dominant driving force behind many management decisions and fundamental to business is turning a profit. In non-profit healthcare facilities, it is a contribution to margin. Decision analysis is the general name that is given to techniques for analysing problems that contain risk/uncertainty/ probabilities. The clinical Engineering department plays a significant role in providing the analytic work to support decision making through a variety of decision analysis techniques. For example, consider a radiology service that has purchased a new Computed Tomography (CT) scanner in addition to their current machine to meet increasing demand. Each unit takes a different length of time to scan the patient. The reality is that there are stochastic processes at work that cause delays that are variable in duration and not evenly distributed on a per patient basis. This can result in as much as a reduction initialisation, or some patients per day. (Seaman, 2005)

2.4.5 Decision Trees

Seaman (2005) describes decision trees are one specific decision-analysis technique. To view this problem, consider the decision tree has three components:

1. Decision nodes that represent points at which the organisation must choose one alternative from some possible options (e.g., at the first decision node, the organisation must select one of the two alternatives choices)
2. Chance nodes represent points at which chance, or probability, plays a dominant role and that reflect alternatives over which the organisation has (effectively) no control.
3. Terminal nodes represent the ends of paths from left to right, through the decision tree.

2.4.6 Decision Support Systems in Maintenance

Blumberg (2005) describes that a significant increase in the development, application, and use of advanced diagnostics and artificial intelligence technology in field service. Research carried out service problem diagnostics that could result in avoidance of between 30% and 35% of all on-site field service calls, and that in-depth diagnostic evaluation could significantly reduce the number of “broken” field service calls through more reasonable dispatch and assignment of both parts and service engineers. Since that discovery, there has been a great deal of work carried out attempting to both develop and apply advanced diagnostics technology in the field service industry. It is, therefore, of value to examine both the current state-of-the-art and the experience in the application and use of problem diagnostics and resolution technology in the health equipment field service industry, as well as to pragmatically explore both the successes and failures of artificial intelligence and advanced remote diagnostics and decision support methodology in service.

2.4.6.1 Remote Diagnostics

The role of artificial intelligence (AI) and remote diagnostics in the service environment is usually part of the overall call-managing process and is based on the strategic use of information and data acquisition methods to identify, isolate, analyse and, ultimately, diagnose and evaluate a fault within a unit of equipment or system. The goal is to increase the efficient allocation and timeliness of service-oriented resources and to raise the productivity of the service force and the uptime of equipment through efficient use and deployment of service personnel and parts to support the uptime objective. Improving performance in the service function relies on having the most efficient technology to find, identify, isolate, predict, and repair a fault or potential fault. This

requires a service organisation of such sophistication as to fully exploit the available and potential benefits of the diagnostic maintenance practice in technological depth. (Blumberg, 2005)

2.4.6.2 Remote Diagnostics Systems

Blumberg (2005) describes that within the specific active remote diagnostic advisory systems are more distinct mechanisms, including General fault models, troubleshooting models, and broad casual models.

The differences between these approaches are outlined below:

1- General fault models: show all the ways that a device can fail and the casual linking among the failures. Information about appropriate tests and repairs is attached to each fault situation. This approach is not very useful for new products and technologies to repair diagnostics.

2- Troubleshooting models: are usually augmented fault models that follow the pattern of the general fault model above but also describe how the fault diagnostics strategy should be modified, under certain conditions. In general, troubleshooting models add “if-then” logic to the standard fault model to support repair analysis.

3- Deep casual models: describe the way the unit under repair is structured and assembled. The knowledge base represents the way the device is put together, the way it works, what the relationships are, how likely each piece is to fail, and generates a troubleshooting strategy, based on these relationships. These models are most often used where the equipment being diagnosed is very new or highly complex or where little or no practical troubleshooting strategy currently exists. (Blumberg, 2005).

2.5 Summary of the Chapter

The summary of the chapter is reviewing the theoretical background of the study. This includes three sections; an overview, medical devices maintenance and decision support system. The overview of medical devices maintenance reviewing of the background that includes biomedical and clinical engineering, the functions and the responsibilities of the clinical engineering department, medical devices management that covers medical devices planning, technical asset management, the technology

evaluation and procurement, medical devices maintenance. The second section in this chapter covers medical devises maintenance in Saudi Arabia which includes; healthcare in Saudi Arabia, medical devises maintenance and clinical engineering departments in Saudi Arabia, the clinical engineering program indicators. The third section is an overview of decision support systems that include the definition, structure, applications in clinical engineering and medical devices maintenance.

CHAPTER 3: GOOD PRACTICES IN MEDICAL DEVICES MAINTENANCE

3.1 Introduction

In this chapter, a review for good international, national practices in medical devices maintenance and research papers in good practices in a decision support system for medical devices maintenance. In this section, a review of good international practices in medical devices maintenance. These practices are organised into four categories:

1- Good national practices from Saudi Arabian organisations.
2- Good international practices from international organisations.
3- Postgraduates' dissertations include master's and PhD thesis.
4- Technical academic papers.

3.2 Good National Practices in Medical Devices Maintenance

In this section, a review for good national practices in medical devices maintenance

1. [Guideline of Professional Classification and Registration For Health Practitioners (The Saudi Commission for Health Specialties, 2015)]: The Saudi Commission for Health Specialties has produced this modified version of the guideline booklet to be consistent with domestic and international health education outputs, and has approved several criteria for ensuring accuracy and objectivity in estimating prior practical experience and training for the obtaining of certificates and professional training. The commission considers the minimum criteria for scientific qualification for any professional ranking to be the predetermined programs in the kingdom of Saudi Arabia, which are the measures according to which all certificates are classified. The commission asserts that this version was revised and audited by specialists in the commission committees and the professional classification committee, as well as being the product of remarks noted down by the commission since the issuance of the fifth edition in 1430AH (2010) and its subsequent organizing regulations in the field of professional classification and registration. Also, this version observes the new developments in the field of scientific certificates relevant to professional health

practice. This version is also subject to amendment and development following progress in the field of medical education and its outputs. The followers and those concerned shall be allowed to review any amendments which may be added to this report via the circular's publication issued by the commission, which shall be added to the commission's website: www.scfhs.org.sa. Finally, the Saudi Commission for Health Specialties hopes that it has managed to achieve its stated goals in creating this modified version of the guideline booklet.

2. [Guidelines for Best Practices in Medical Device Management within Healthcare Facilities (SFDA, 2018)]: Saudi FDA recognized the importance of this issue, Saudi FDA formed a team of experts to gather the best practices around the world in Medical devices management and local stories of success within Saudi Arabia to develop a guideline that could help healthcare facilities in safe and effective management of their technology. The objectives of these guidelines are to develop unified national guideline for best practices in medical device management throughout their life cycle within healthcare facilities, to develop guidelines for health technology assessment as a continuous tool for effective planning and management of health Technologies, and to enhance the effectiveness and improve the management of medical devices, their operation and their rational use within healthcare facilities. This guideline applies to any medical device used as part of the routine care of patients. It will provide procedures and practices that will help ensure that a medical device is managed, operated and maintained as recommended by the manufacturer to ensure that its performance will be maintained throughout its lifetime. The procedures will cover the medical device life cycle.

3. [Maintenance, Cleaning and Non-medical Operation and Maintenance Manual (Ministry of Health, 2013)]: The Maintenance General Department in the Assistant Agency for Engineering Affairs has recently released the Directory of Maintenance, Cleaning, Non-Medical Operation and Medical Maintenance Procedures. This Directory is reckoned one of the key documents at any of the Kingdom's hospitals. It is a paper manual, comprising the instructions and procedures that should be followed during any maintenance, cleaning operation of non-medical maintenance and cleaning contracts at hospitals. Moreover, the Directory, in general, covering the way of undertaking tasks and duties assumed by the maintenance and cleaning staff at hospitals. It is worth mentioning that this Directory aims at unifying the work procedures in the maintenance field, the workflow, as well as identifying the responsibilities and tasks of each function of maintenance processes. Furthermore,

the Directory aims at the assignment of responsibilities when there are irregularities or noncompliance with procedures, instructions and regulations, aside from identifying the mutual relations and activities between different departments and showing the work system and maintenance procedures for those recently hired employees. This manual is available only in Arabic only,

4. **[National Standards for Hospitals (CBAHI, 2014)]:** The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) is the official agency authorised to grant accreditation certificates to all governmental and private healthcare facilities operating today in Saudi Arabia. CBAHI has emerged from the Saudi Health Council as a non-profit organisation. The principal function of CBAHI is to set the healthcare quality and patient safety standards against which all healthcare facilities are evaluated for evidence of compliance. Healthcare accreditation is an assessment process that involves a rigorous, transparent, and comprehensive evaluation by an external independent accreditation body. The healthcare facility undergoes an examination of its systems, processes, and performance by peer reviewers or surveyors to ensure that all is conducted in a manner that meets applicable predetermined and published national standards. Before the external evaluation, i.e., the survey visit, the healthcare facility is expected to conduct a comprehensive self-assessment to decide on the level of its preparedness and how far or how close it is from achieving full compliance with the standards. Accreditation, therefore, represents a public recognition by the healthcare accreditation body of satisfactory achievement of accreditation standards by a healthcare facility. This program was launched for all hospitals in the public and private sector in the Kingdom that provides secondary, tertiary, and Quaternary levels of healthcare services.

5. **[National Transformation Program 2020, (Council of Economic and Development Affairs, 2016b)]:** The National Transformation Program was developed to help fulfil “Saudi Arabia’s Vision 2030” and to identify the challenges faced by government bodies in the economic and development sectors. The program establishes strategic objectives that are based on the Vision and addresses its challenges through 2020 following specific targets. The program identifies, each year, the initiatives necessary for achieving such goals and devises detailed plans based on interim indicators that measure and monitor performance. In its first year, the program was launched across 24 government bodies, and there are plans to expand its coverage annually. The National Transformation Program will develop government action and establish the necessary foundations to accommodate its ambitions and

requirements. This will help fulfil the ambitions of the Vision. The first wave toward this goal will encompass program initiatives for 2016. These will be reviewed and evaluated, and their adequacy and performance will be measured regularly. Furthermore, new initiatives will be considered for adoption into the National Transformation Program.

6. **[Quality of Life Program 2020 (Council of Economic and Development Affairs, 2016b)]:** The Council of Economic Affairs and Development has defined 12 Vision Realization Programs of strategic importance for the government of Saudi Arabia in order to achieve the objectives established in Vision 2030. Among those 12 Programs is the Quality of Life Program 2020. This Program mainly focuses on making Saudi Arabia a top living destination for both Saudi citizens and residents. Based on the Program description within the Program card, this Program will focus on two aspects: improving individuals' lifestyle –Developing an ecosystem to support and create new options that boost citizens' and residents' participation in cultural, entertainment, and sports activities, enhancing quality of life, enveloping suitable activities that contribute to enhancing the quality of life of individuals and families, creating jobs, diversifying economic activity, and boosting the status of Saudi Arabian cities so that they rank among the best cities in the world.

7. **[Saudi Arabia's Vision for 2030, (Council of Economic and Development Affairs, 2016)]:** Saudi Arabia's Vision for 2030 is a strategic plan for the country which called "Vision 2030" that focuses on three themes: a vibrant society, a thriving economy and an ambitious nation. This first theme is vital to achieving the Vision and a strong foundation for economic prosperity. It is essential for a vibrant society. Members of this society live by the Islamic principle of moderation, are proud of their national identity and their ancient cultural heritage, enjoy a good life in a beautiful environment, are protected by caring families and are supported by an empowering social and health care system. In the second theme, a thriving economy provides opportunities for all by building an education system aligned with market needs and creating economic opportunities for the entrepreneur, the small enterprise as well as the large corporation. Therefore, it will develop the investment tools to unlock the promising economic sectors, diversify the economy and create job opportunities. It will also grow the economy and improve the quality of the services, by privatising some government services, improving the business environment, attracting the most exceptional talent and the best investments globally, and leveraging the unique strategic location in connecting three continents. The third theme is built on a practical,

transparent, accountable, enabling and high-performing government. This will also prepare the right environment for the citizens, private sector and non-profit sector to take their responsibilities and take the initiative in facing challenges and seizing opportunities. In each of these themes, highlighted a selection of commitments and goals, as a reflection of its ambition and a representation of what it aims to achieve. This Vision will be the point of reference for future decisions so that all future projects are aligned to their content. So, the vision will achieve its goals by apply efficiency and responsibility at all levels. (Council of Economic and Development Affairs, 2016a).

The discussion for the previous good national practices in medical devices maintenance that had shown general guidelines and practices in medical devices maintenance but most of them had discussed one or more factors that affect the quality but none of them had come up with wide range or a full image explanation or full image of designing a decision support system to improve medical devices maintenance in general or for a developing country like Saudi Arabia which this study focus on.

3.3 Good International Practices in Medical Devices Maintenance

1. [Best Practices for Medical Technology Management: A U.S. Air Force-ECRI Collaboration (Keller JP Jr and Walker S. 2005)]: For more than 25 years, the U.S. Air Force has contracted ECRI, an independent and non-profit health services research agency, to disseminate patient safety medical device information to key staff at all Air Force hospitals worldwide. The nature of the information includes product recalls, notices regarding medical device hazards, product evaluations, guidance on the safe selection and use of medical devices, and systematic processes for managing hazards and recalls in an institutional health care environment. The information is used by biomedical engineering professionals, logistics personnel, clinicians, and administrators in support of the medical technology management programs in their hospitals. This article will discuss the use of this information in Air Force clinical facilities and the role of the Air Force Medical Logistics Office (AFMLO) in this communication process. It also will examine new electronic tools for managing medical device hazards, recalls, and other device-related patient safety information. The program featured in this discussion central to the Air Force's longstanding commitment to appropriate and consistent medical device safety management at each of its

hospitals. It is a program that relies heavily on an independent investigation to clarify medical device problems, including unbiased research into device performance and comparative product evaluations. Standardised naming conventions are used for hazard and recall notifications. Additionally, inventory databases are used to identify problematic devices in each hospital, while technical experts on a wide variety of medical technologies consider the suspect devices. The Air Force collaboration with ECRI has led to the development of a “best practice” for the management and dissemination of medical device patient safety information from which the entire health care industry can benefit. (Keller JP Jr and Walker S. 2005)

2. **[Biomedical Benchmark (ECRI, 2016a)]**: Biomedical Benchmark is a clinical engineering performance web-based system that provides the information to make well-informed, data-driven decisions managing medical equipment and service activities. This includes model-specific equipment maintenance data, representative equipment acquisition and service contract costs, user-generated procedures, expected product life data. Benchmark helps to identify best practices in clinical engineering (CE) from around the world to compares the facility to others of similar size and circumstance with the data from both ECRI Institute and healthcare facility to be able to gauge organisational efficiency and improve specific performance areas with: CE department staffing and inventory size demographics, an analysis of non-maintenance activities, expected equipment life estimates, and best practice tips. The system provides comprehensive inspection and preventive maintenance and providing essential details, such as required test equipment, precautions, instructions, and suggested inspection intervals—helping streamline scheduled maintenance activities and ensure operational consistency. Each procedure is customisable to fit your facility’s needs and be able to modify existing procedures and develop additional procedures. (ECRI, 2016a).

3. **[Computerised maintenance management system (WHO, 2011a)]**: With the expansion of health facilities and the number of medical devices, they depend on the provision of qualitative increases in health care and the need to manage health care technology more effectively and efficiently. Computerised Maintenance Management System (CMMS) is a tool that can improve the management of medical equipment in general at the enterprise level. The information contained in the CMMS varies depending on the individual case but always includes medical device inventory and usually includes information such as service history, preventive maintenance procedures, equipment, performance indicators, and cost information. CMMS consists

of fields, tables and units populated with data from the Department of Clinical Engineering or Medical Devices at a facility. Using CMMS, critical data can be accessed, processed and analysed using user-friendly interfaces. Reports can be generated from the system to assist policymakers in reaching decisions on health technologies. However, it is essential to consider several factors when deciding to adopt and develop CMMS. Factors such as financial and technical resources are essential in determining whether to buy a commercial product, use open source software, or develop a system locally. Implementation requires follow-up through a few stages that will allow comprehensive system planning. By completing this multi-step process, deployment options will be evaluated accurately; an appropriate package will be selected, installed and customised; data will be entered; CMMS training will be provided. For organisations with the appropriate resources to implement this tool, CMMS can be handy. It is when properly implemented, can transform medical equipment management while improving the availability of functional technology needed to prevent, diagnose and treat diseases. (WHO, 2011a).

4. **[Development of medical device policies (WHO, 2011b)]:** Policies create a framework through which valuable resources are channelled. The National Health Policy Framework includes a vision and analysis of the status and policy trends, strategies to overcome challenges, and a plan for policy implementation, leadership and governance for sustainability. When included in national health policy, health technology policies can be linked to the components of other health systems, human resources, information, leadership and governance - which together address the needs of the target population and may lead to better health outcomes. Effective health technology policies address inequities, as well as access, affordability, and the availability of innovative and essential medical devices to target health needs, particularly those that address the Millennium Development Goals and noncommunicable diseases. To achieve this, the four phases of medical devices - research and innovation, the organisation of device safety, better assessment of decision-making, overall management and adaptation to public health conditions, resources and priority settings - must be studied. Once policies are consolidated, organisational structures must implement the strategies and action plans contained therein. This includes regulatory authority and regional and national institutions for optimal health technology assessment and management, supported by specialists in biomedical engineering and related fields. Monitoring and evaluating strategies and

targets or action plans and using indicators to track impact will increase accountability and provide feedback for policy improvement and implementation. (WHO, 2011b*).*

5. [Health Devices System (ECRI, 2016b)]: A health technology management suite offering medical product test results and ratings, an early warning system of device safety alerts, expert technical guidance, free consultations and webinars, and further invaluable tools and resources. The Health Devices system supports Procurement, Clinical Engineering and Risk Management departments to help navigate today's complex health technology challenges. Evaluations and guidance, test results, product ratings, and unbiased recommendations for safe, cost-effective management of today's sophisticated medical technologies, Top 10 health technology hazards. Popular annual list of potential dangers associated with the use of medical devices and recommendations to help healthcare providers minimise the risk of technology-related adverse events, Consultation services. Personal, expert advice on high impact medical technology topics, from wireless networking and interoperability to smart infusion pumps, Healthcare product alerts. Safety alerts covering medical device problems, field corrections, and recalls, with recommendations for follow-up, Web conferences on critical healthcare technology topics. (ECRI, 2016b).

6. [Health Technology Assessment of Medical Devices (WHO, 2011c)]: This document integrates the World Health Organisation (WHO) Health Technology Assessment into evidence-based policy development. Health systems are strengthened when the health technology assessment integrated into human and material resources, data, decision-making and decision-making are transparent and linked to the overall vision of equality and accountability. Good governance can rely on a health technology assessment to provide policy approaches that are responsible for its decisions towards the population.

7. Healthcare Technology Management (HTM) Benchmarking Guide, (AAMI, 2018)]: Healthcare Technology Management (HTM) programs are growing and need to do so efficiently. Benchmarking allows some guidelines and relevant comparisons to similar organisations (peers) to be made regarding staffing and other factors in growing HTM or Clinical Engineering programs. Multiple metrics are needed to measure how well an HTM program operates accurately. Financial performance, customer service, equipment uptime, and other indicators are needed. For example, the cost-of-service ratio (COSR); the ratio of the total of all internal and external service costs and repair parts costs divided by the total of all medical device acquisition costs—continues to be the best- established financial performance metric. Device count is a

poor workload indicator unless the equipment in the workload is of similar cost and complexity. AAMI's HTM Levels Guide defines three HTM program levels: Level 1 – Fundamental: These programs provide a basic level of technology services and compliance with applicable standards and regulations. Level 2 – Established: Programs at this level have moved beyond the basics to provide additional services, with a focus on cost-effectiveness. Level 3 – Advanced: These programs are on the leading edge, demonstrating the full range of potential for HTM contributions to patient care. (AAMI, 2018).

8. **["How to Manage" Series for Healthcare Technology - Guide 01: How to Organize a System of Healthcare Technology Management (Lenel et al.,2005)];** This series of guides (a set of six Guides) on how to manage healthcare technology is funded by the UK Department for International Development (DFID) for the benefit of developing countries, although they may also be relevant to emerging countries. Guide 1 covers the framework in which Healthcare Technology Management (HTM) can take place. It also provides information on how to organise a network of HTM Teams throughout the health service provider organisation. Guide 1 covers the framework in which Healthcare Technology Management (HTM) can take place. It also provides information on how to organise a network of HTM Teams throughout the health service provider organisation. (Lenel A. et al.,2005).

9. **["How to Manage" Series for Healthcare Technology - Guide 02: How to Plan and Budget for Your Healthcare Technology (Temple-Bird et al.,2005a)]**:This series of guides (a set of six Guides) on how to manage healthcare technology is funded by the UK Department for International Development (DFID) for the benefit of developing countries, although they may also be relevant c. Guides 2 is resource materials which will help health staff with the daily management of healthcare technology. It covers the chain of activities involved in managing and how to plan and budget for healthcare technology. (Temple-Bird C. et al.,2005a)

10. **["How to Manage" Series for Healthcare Technology - Guide 03: How to Procure and Commission Your Healthcare Technology (Kaur et al.,2005)]:** This series of guides (a set of six Guides) on how to manage healthcare technology is funded by the UK Department for International Development (DFID) for the benefit of developing countries, although they may also be relevant to emerging countries. Guides 3 is resource materials which will help health staff with the daily management of healthcare technology. It covers the chain of activities involved in managing and how to procure and commission healthcare technology. (Kaur M. et al.,2005).

11. [“How to Manage" Series for Healthcare Technology - Guide 04: How to Operate Your Healthcare Technology Effectively and Safely (Temple-Bird et al.,2005b)]: This series of guides (a set of six Guides) on how to manage healthcare technology is funded by the UK Department for International Development (DFID) for the benefit of developing countries, although they may also be relevant to emerging countries. Guides 4 is resource materials which will help health staff with the daily management of healthcare technology. It covers the chain of activities involved in managing and how to operate Healthcare technology effectively and safely. (Temple-Bird C et al.,2005b)

12. [“How to Manage" Series for Healthcare Technology - Guide 05: How to Organize the Maintenance of Your Healthcare Technology (Temple-Bird et al.,2005c)]: This series of guides (a set of six Guides) on how to manage healthcare technology is funded by the UK Department for International Development (DFID) for the benefit of developing countries, although they may also be relevant to emerging countries. Guides 4 is resource materials which will help health staff with the daily management of healthcare technology. It covers the chain of activities involved in managing and how to organise the maintenance of healthcare technology. (Temple-Bird C. et al.,2005c).

13. [“How to Manage" Series for Healthcare Technology - Guide 06: How to Manage the Finances of Your Healthcare Technology Management Teams (Kawohl et al.,2005)]: This series of guides (a set of six Guides) on how to manage healthcare technology is funded by the UK Department for International Development (DFID) for the benefit of developing countries, although they may also be relevant to emerging countries. Guide 6 looks at how to ensure Healthcare Technology Management (HTM) Teams carry out their work in an economical way, by advising financial management. Guide 6 looks at how to ensure HTM Teams carry out their work in an economical way, by advising financial management. (Kawohl W., et al.,2005).

14. [Human Resources for medical devices, the role of Biomedical Engineers (WHO, 2017)]: This book is part of the Medical Device Technical Series to provides various roles that a biomedical engineer can perform in the life cycle of a medical device, from conception to use. This book is two parts. The first look at the biomedical engineering profession globally as part of the health workforce: global figures and statistics, occupational classification, general education and training, professional associations, and certification process. The second part of this book deals with all the

different roles a biomedical engineer can have in the life cycle of technology, from Research and Development (R&D) and innovation, which is implemented primarily in academia, regulation of devices entering the market; evaluation or assessment of the selection and prioritization of medical devices (usually at the national level); the role they play in the management of equipment from choice and procurement to safe use in health care facilities. Finally, the annexes provide comprehensive information on academic programs, professional associations, WHO, and United Nations documents related to human resources for health, as well as the International Labour Organisation's (ILO) reclassification proposal. This publication can be used to promote the availability, recognition and participation of biomedical engineers as part of the health workforce, particularly after the adoption of the recommendations of the United Nations High-level Committee on Economic Employment and Growth, the WHO Global Strategy. On human health resources, and the establishment of national health workforce accounts. The document also supports the objective of re-categorising the biomedical engineer role as an engineer supporting the development, access and use of medical devices within the national, regional and World Health Organisation (WHO). (WHO، 2017).

15. [Introduction to medical equipment inventory management (WHO, 2011d)]: Equipment inventory is an essential part of an effective health-care technology management (HTM) system. In order to be effective in assisting with various HTM activities, the inventory must be updated continually so that it provides at any given moment a right look at the status of medical equipment within the health-care facility. Update points include initial data collection; as information is updated, such as when a new piece of equipment arrives or is retired; and during annual inventory audits. The inventory of medical equipment is used in conjunction with the inventories of additional supportive assets, such as consumables, spare parts, and testing and safety tools and equipment. The inclusion of equipment in an inventory is decided through a risk-based analysis in order to ensure appropriate time and resource allocation and to eliminate unnecessary work. The health-care facility decides on the level of detail of data to be included in its inventory, in order to satisfy its requirements and according to its capabilities. Inventory management is done through a paper-based or computer-based system, as determined by the resources available. Once established, the inventory serves as the foundation for moving forward within the HTM system and ensuring safe and effective medical equipment. The inventory may be used to develop budgets for capital purchases, maintenance and running costs; to build and support an active

clinical engineering department, by allowing for workshop planning, hiring and training of technical support staff, and establishing and maintaining service contracts; to support an effective medical equipment management programme, such as planning preventive maintenance activities and tracking work orders; and to plan the stock of spare parts and consumables. The inventory may also be used to support equipment needs assessment within the health-care facility and to record the purchase, receipt, retirement and discarding of equipment. Facility risk analysis and mitigation, and emergency and disaster planning, are also supported by an inventory. (WHO, 2011d).

16. [Joint Commission International Accreditation Standards for Hospitals (JCI, 2013)]: The mission of Joint Commission International (JCI) is to improve the safety and quality of care in the international community through the provision of education, publications, consultation, and evaluation services. Joint Commission Resources educational programs and publications support but are separate from, the accreditation activities of Joint Commission International. Attendees at Joint Commission Resources educational programs and purchasers of Joint Commission Resources publications receive no special consideration or treatment in, or confidential information about, the accreditation process. This edition contains the standards, intents, measurable elements (MEs), a summary of fundamental changes to this edition of the Joint Commission. International (JCI) hospital standards, a summary of crucial accreditation policies and procedures, a glossary of key terms, and an index. JCI requirements are described in these categories: Accreditation Participation Requirements (APR), Standards, Intents, Measurable Elements (MEs) **(**JCI, 2013).

17. [Managing Medical Devices: Guidance for healthcare and social services organisations (MHRA, 2015)]: The purpose of this document is to outline a systematic approach to acquisition, deployment, maintenance (preventive maintenance and performance assurance), and medical device repair and disposal. It also provides instructions on training in medical devices. It is primarily intended for people in hospital and community organisations that are responsible for managing reusable medical devices, for helping them develop and develop systems that promote the use of medical devices for safe and effective health. Many of the principles of this guidance document may apply to all medical devices. However, all sections may not apply to implantable devices, and diagnostic medical devices are covered in separate documents. Medical devices play a crucial role in health care and are essential for diagnosis, treatment, surveillance, rehabilitation and care. Effective management of this vital resource is required to meet high-quality patient care, clinical and financial

governance, including minimising the risk of adverse events. Unless medical devices are managed proactively, the same types of adverse events occur repeatedly. Managing good medical devices will significantly help reduce their potential for harm. (MHRA, 2015).

18. [Medical device regulations: global overview and guiding principles, (WHO, 2003)]: The organisation of medical devices is a vast and rapidly evolving field, often complicated by legal technologies. For example, legal terminology and its meanings are sometimes not uniform even under a single regulatory regime. In an attempt to make this complex subject easier to understand, this guide provides a common framework for regulatory systems for the five countries or regions with the most advanced systems of medical devices. Non-technical language, graphics, tables and memory anchors are used to provide an overview of medical device safety issues and organisational philosophy. The guide begins by explaining the safety of risk management and how safety and optimum performance require collaboration among all participants in the life span of a medical device. Critical elements of medical device regulations are clarified using a common framework for organisational development, as well as current the Global Harmonization Task Force (GHTF) regulatory tools and all major documents issued in the last three years. Understanding the different stages in the life span of a medical device and common framework is one of the first steps to successfully achieve harmonisation and simplification around the world. (WHO, 2003)

19. [Medical equipment maintenance programme overview (WHO, 2011e)]: Medical devices are the assets that directly affect human life. They are large investments, and in many cases, high maintenance costs. Therefore, it is important that they have a well-planned and managed maintenance program that can keep medical equipment in a health care institution reliable, safe and available for use when needed for diagnosis, treatment, treatment and monitoring. Of patients. Also, this program extends the useful life of equipment and reduces the cost of equipment ownership. The maintenance strategy includes screening procedures as well as preventive and corrective maintenance. Performance Checks Ensure equipment is working properly, and safety inspections ensure that equipment is safe for both patients and operators. Preventive maintenance (PM) aims to prolong the life of equipment and reduce failure rates. Additionally, some hidden problems may be discovered during a scheduled inspection. However, the conduct of inspections only ensures that the device is in good working condition at the time of examination and can eliminate the possibility of failure during future use; the nature of most electrical

and mechanical components is that they can fail at any time. Corrective maintenance (CM) repairs a failed machine function and allows it to be restarted. An effective medical equipment maintenance program consists of appropriate planning, management and implementation. Planning takes account of the financial, material and human resources necessary to carry out maintenance activities appropriately. Once the program is identified, financial, personnel and operational aspects are continuously examined and managed to ensure uninterrupted program continuity and improvements as necessary. In the end roper implementation of the program is key to ensuring optimal equipment performance. (WHO, 2011e)

20. [Needs Assessment for Medical Devices (WHO, 2011f)]: Needs assessment is a complex process, incorporating several variables, that provides decision-makers with the information necessary to prioritise and select appropriate medical devices at a national, regional or hospital level. This document describes and illustrates the objective, the general approach and the process of such a needs assessment. The central section, Specific approach, demonstrates in seven steps how to identify related needs, consider the requirements of baseline information, analyse the gathered information, appraise the options, and prioritise the specific requirements. Tools are being continuously developed to support this decision-making process, and this document also includes information on useful tools that will help in the execution of these steps. (WHO, 2011f).

21. [Practicum for Healthcare Technology Management, (AAMI 2015)]: This textbook published by the Association for the Advancement of Medical Instrumentation as a resource for biomedical professionals. It covers Healthcare Technology Management from The Joint Commission accreditation process and managing medical device safety to human factors engineering and evidence-based medical equipment maintenance management. It is a Practicum for Biomedical Engineering and Technology Management had written by experts in the profession, This publication includes chapters on: Quality assurance, Establishment of an in-house biomedical program, Use errors, Wireless spectrum management, Medical equipment replacement, Failure mode and effects analysis (FMEA), Introduction to imaging devices, Customer satisfaction, This book is an invaluable resource for the department, classroom, or professional library. (AAMI 2015).

22. [Procurement Process Resource Guide (WHO, 2011g)]: It is an effective procurement practice in health technology lead to the provision of safe, fair and quality health care, and all stakeholders have the benefits of gaining procurement staff by

doing clear and accountable work for internationally accepted standards; funding agencies can trust the right goods purchased at the right price Health service professionals receive high-quality materials and tools; more importantly, patients can have access to appropriate and effective health care. Poor procurement practices have led to substandard provision or performance of health technology. This document summarises the resources currently available to achieve good practices in this area. This will serve as a checklist and assistance planning for the development of the procurement system but will also guide the user to more detailed information on each part of the procurement cycle. Section 6 of this document describes the following standard procurement procedures: technology assessment; machine assessment planning and needs assessment; management; installation; commissioning; monitoring. Section 7 discusses resources that will assist in the following issues: local regulations; replacement equipment refurbished equipment radiological equipment health information technology; utilities and construction. Emergencies; sustainability; e-procurement. Grievances; ethical considerations. Section 8 describes procurement performance evaluation systems, which are used to improve existing structures, enhance efficiency and transparency. (WHO, 2011c).

The discussion for the previous good international practices in medical devices maintenance had shown general guidelines and practices in medical devices maintenance but most of them had discussed one or more factors that affect the quality but none of them had come up with wide range or a full explanation or designing a decision support system to improve medical devices maintenance in general or for a developing country like Saudi Arabia which this study aims to.

3.4 Good Academic Research Papers

In this section, a review for some previous studies that show good practices in the decision support system for medical devices maintenance:

1. [Adapting the IDEAL Framework and Recommendations for medical device evaluation: A modified Delphi survey (Pennell, Hirst, Sedrakyan, & McCulloch, P.G. 2016)]: Current regulatory systems for medical device marketing approval lack adequate requirements for evidence of safety and efficacy. The Total Product Life Cycle (TPLC) concept, with clinical use and marketing expanding as evidence develops, has won support but lacks a template to define evidence requirements at

different stages. The IDEAL Framework & Recommendations, originally developed for new surgical procedures, might provide such a template, but may require modification. The study conducted a Delphi expert consensus exercise to determine how IDEAL might be modified to accommodate the needs of device regulation. Thirt four experts were invited to participate in 3 rounds of questioning, with feedback of the results of each round to participants before the next. The study found that 27 of 34 experts responded in at least one survey round. Experts agreed that, after appropriate modifications, IDEAL could form an evidence template for a TPLC-based regulatory system. Necessary modifications include a new Stage 0 should guide reporting of pre-clinical studies, expansion of registries to all stages, and omission of IDEAL stages 2 and 3 for “successor” devices under certain conditions. A standard approach to TPLC evaluation of medical devices does not currently exist. The IDEAL Framework, if modified appropriately, could fill such a void and improve the safety of new medical devices.

2. **[An Intelligent Healthcare Management System: A New Approach in Work-order Prioritization for Medical Equipment Maintenance Requests (Hamdi, N et al., 2012)]:** The effective maintenance management of medical technology influences the quality of care delivered and the profitability of healthcare facilities. Medical equipment maintenance in Jordan lacks an objective prioritisation system; consequently, the system is not sensitive to the impact of equipment downtime on patient morbidity and mortality. The current work presents a novel software system (EQUIMEDCOMP) that is designed to achieve valuable improvements in the maintenance management of medical technology. This work-order prioritisation model sorts medical maintenance requests by calculating a priority index for each request. Model performance was assessed by utilising maintenance requests from several Jordanian hospitals. The system proved highly efficient in minimising equipment downtime based on healthcare delivery capacity, and, consequently, patient outcome. Additionally, a preventive maintenance optimisation module and an equipment quality control system are incorporated. The system is, therefore, expected to improve the reliability of medical equipment and significantly improve safety and cost-efficiency.

3. **[Computer-Aided Planned Maintenance System for Medical Equipment (Müldür, 2003)]:** In this study, a software package is introduced, which has been developed to monitor and administer preventive maintenance activities for healthcare devices and system components in a hospital to provide uninterruptible operation in a computer-aided fashion. This software with its object-oriented and graphic user

interface (GUI) nature aims to standardise preventive maintenance activities while providing overall optimisation of material used in preventive maintenance activities; personnel administers the maintenance and time dedicated for the activities.

4. **[Design of a decision support system for preventive maintenance planning in health structures (Miniati, Dori, & Gentili, 2012)]:** The appropriate maintenance of medical devices, including performance inspections and preventive maintenance, is fundamental in mitigating clinical risk caused by adverse events in health care. Although several models for managing and planning preventive maintenance have been developed, the problem is lacking in standard methodology and still presents an open challenge for today's health experts. This study aims to provide and develop methodology together with support systems able to assist decision makers in constructing preventive maintenance and performance inspection plans, considering both the technical and economic needs of hospital clinical engineering departments. Interventions by decision makers are of crucial importance within complex situations where large numbers, types of devices and different contractual situations are involved. This system has achieved optimal results with minimum expense and maximum security for patients and technicians at the University Hospital of Florence where it has been applied in actual case studies.

5. **[Exploring new roles for case-based reasoning in heterogeneous AI systems for medical decision support (Montani, 2008)]:** Background Supporting medical decision making is a complex task, that offers challenging research issues to Artificial Intelligence (AI) scientists. The Case-based Reasoning (CBR) methodology has been proposed as a possible means for supporting decision making in this domain since the 1980s. Nevertheless, despite the variety of efforts produced by the CBR research community, and the number of issues handled adequately by means of this methodology, the success of CBR systems in medicine is somehow limited, and almost no research product has been thoroughly tested and commercialized; one of the main reasons for this may be found in the nature of the problem domain, which is extremely complex and multi-faceted. Materials and methods in this environment, it proposes to design a modular architecture, in which several AI methodologies cooperate, to provide decision support. In the resulting context CBR, originally conceived as a well-suited reasoning paradigm for medical applications, can extend its original roles, and cover a set of additional tasks. Results and conclusions as an example, the paper will show how CBR can be exploited for configuring the parameters relied upon by other (reasoning) modules. Other possible ways of deploying CBR in this domain will be the

object of future investigations, and, in the opinion, a possible research direction for people working on CBR in the health sciences.

6. **[Intelligent decision support system for diagnosis and maintenance of automated systems (Patel & Kamrani, 1996)]:** ROBODOC, the diagnosis and maintenance consultant, is an off-line decision support utility that will help maintenance staff diagnose and correct robotic failures. It uses a group technology approach to classify symptoms and a decision tree approach in developing the system. It can produce both detailed as well as shallow reports of problems and their fixes. Its modularity makes it easier to add or revise the knowledge base or to transfer the diagnostic knowledge from one automated system to another, without necessitating complete development from scratch. The results of this work can contribute to the development of a design for a service expert system, which will be able to give design recommendations based on past experiences, which will produce more durable and more comfortable to maintain equipment designs.

7. **[Medical device maintenance outsourcing: Have operation management research and management theories forgotten the medical engineering community? A mapping review (Cruz & Rincon, 2012)]:** This paper examines the large body of existing research on outsourcing and assesses the status of research on outsourcing the maintenance of medical devices. Because so little research in this area currently exists, the study was broadened to include other fields that outsource maintenance services and considers possible applications to the field of medical device maintenance. In all, this paper examines 55 articles spanning various dimensions, including mathematical models, empirical studies, and conceptual papers. The study concluded that research into the outsourcing of medical device maintenance services in hospitals is still in its infancy stages and that further progress in this field would benefit from additional empirical study grounded in management theory.

8. **[Medical Device Risk Management for Performance Assurance Optimization and Prioritization (Gaamangwe et al. 2015)]:** Performance assurance (PA) is an integral component of clinical engineering medical device risk management. For that reason, the clinical engineering (CE) community has made concerted efforts to define appropriate risk factors and develop quantitative risk models for efficient data processing and improved PA program operational decision making. However, a common framework that relates to the various processes of a quantitative risk system does not exist. This article provides a perspective that focuses on medical device quality and risk-based elements of the PA program, which include device

inclusion/exclusion, schedule optimisation, and inspection prioritisation. A PA risk management framework is provided, and previous quantitative models that have contributed to the advancement of PA risk management are examined. A general model for quantitative risk systems is proposed, and further perspective on possible future directions in the area of PA technology is also provided.

9. **[Medical Imaging Devices Assessment at Public Health Sector of Greece. Risk-Based Maintenance: A Decision Support Model (Tsantis & Apostolakis, 2014)]**: Medical imaging equipment such as ultrasound, X-ray, Computed Tomography and Magnetic Resonance Imaging systems are essential in modern hospital operation. They can promote public health under the condition that they operate with high reliability and safety requirements. The study aims to the prerequisites necessitate an efficient maintenance planning that could keep these devices in good condition at the minimum cost. The rare economic resources in Greece due to the recession have made this task rather difficult. The study Methodology: A risk-based decision support model is introduced in this study towards the debate on whether to maintain or not a medical imaging device. Several parameters and metrics have been utilised as an input in the decision algorithm in order to produce an optimum decision regarding the need to maintain a particular device. These include availability, key performance indicators (KPIs), risk and economic factors. These metrics can capture all the information that is significant for each medical imaging device. The study results: A case study has been made in this study that utilised an x-ray imaging C-arm towards efficient decision-making regarding maintenance that employed all the metrics of the last two years where the C-arm imaging device is without a preventive maintenance contract with the manufacturer. Conclusions: The decision model introduced in this study could be of value for hospital management and provide valuable information regarding the condition of each medical imaging device and possible future failures.

10. **[Preventive Maintenance Optimization in Healthcare Domain: Status of Research and Perspective (Mahfoud et al., 2016)]:** Medical equipment maintenance has been carefully managed for years, very few in-depth studies have been conducted to evaluate the effectiveness and efficiency of these implemented preventive maintenance strategies, especially after the debate about the credibility of the manufacturer's recommendations has increased in the clinical engineering community. Facing the dilemma of merely following manufactures maintenance manual or establishing evidence-based maintenance, medical equipment maintenance could have exploited an advanced area in operations research which is maintenance

optimisation research. In this paper, we review and examine the status of application-oriented research on preventive maintenance optimisation of medical devices carefully. This study addresses preventive healthcare maintenance with a focus on factors influencing the maintenance decision making. The analysis is structured by defining different aspects necessary to construct a maintenance optimisation model. We conclusively propose directions to develop suitable tools for better healthcare maintenance management.

11. [Prioritization of medical equipment for maintenance decisions (Taghipour, Banjevic, & Jardine, 2011)]: Clinical engineering departments in hospitals are responsible for establishing and regulating a Medical Equipment Management Program to ensure that medical devices are safe and reliable. In order to mitigate functional failures, significant and critical devices should be identified and prioritised. This study presents a multi-criteria decision-making model to prioritise medical devices according to their criticality. Devices with lower criticality scores can be assigned a lower priority in a maintenance management program. However, those with higher scores should be investigated in detail to find the reasons for their higher criticality, and appropriate actions, such as 'preventive maintenance', 'user training', 'redesigning the device', should be taken. This study also describes how individual score values obtained for each criterion can be used to establish guidelines for appropriate maintenance strategies for different classes of devices. The information of 26 different medical devices is extracted from a hospital's maintenance management system to illustrate an application of the proposed model

12. [Proposal for the Shared Decision-Making Process Regarding Initiation and Continuation of Maintenance Haemodialysis. (Watanabe et al., 2015)]: The study subgroup on withholding and withdrawal of dialysis has been established as a subsidiary organisation of the haemodialysis guidelines commission of the Japanese Society for Dialysis Therapy (JSDT). External members have also joined the discussion, and we have discussed the issue several times. Finally, we have come to present the proposal in this report. The medical team for dialysis treatment should involve, at a minimum, the attending doctor, a nurse, and a clinical engineering technologist, while other individuals can be included by the scale of the institution and number of staff. However, it is recommended that the team include multiple members of each profession. If possible, other healthcare practitioners (such as social workers, dieticians, pharmacists, and a person-in-charge of welfare) should also be part of the medical team. The Guideline Commentary regarding the Decision-making Process at

Terminal Care" released by the Ministry of Health, Labour and Welfare in Japan (MHLW) described that the accurate definition of the terminal stage is difficult.

13. [Reliability analysis of maintenance data for complex medical devices (Taghipour, Banjevic & Jardine, 2011)]: This work proposes a method to analyse maintenance data for sophisticated medical devices with censoring and missing information statistically. It presents a classification of the different types of failures and establishes policies for analysing data at the system and component levels considering the failure types. The results of this analysis can be used as basic assumptions in the development of a maintenance/inspection optimisation model. As a case study, we present the reliability analysis of a general infusion pump from a hospital.

14. [Safety-cost Trade-offs in Medical Device Reuse: a Markov Decision Process Model (Sloan, 2007)]: Healthcare expenditures in the US are approaching $2 trillion, and hospitals and other healthcare providers are under tremendous pressure to rein in costs. One cost-saving approach which is gaining popularity is the reuse of medical devices which were designed only for single use. Device makers decry this practice as unsanitary and unsafe, but a growing number of third-party firms are willing to sterilise, refurbish, and remanufacture devices and resell them to hospitals at a fraction of the original price. Is this practice safe? Is reliance on single-use devices sustainable? A Markov Decision Process (MDP) model is formulated to study the trade-offs involved in these decisions. Several vital parameters are examined: device costs, device failure probabilities, and failure penalty cost. For each of these parameters, expressions are developed which identify the indifference point between using new and reprocessed devices. The results can be used to inform the debate on the economic, ethical, legal, and environmental dimensions of this complex issue.

15. [Stakeholder challenges in purchasing medical devices for patient safety (Hinrichs, Dickerson & Clarkson, 2013.)]: This work identifies the stakeholders who have a role in medical device purchasing within the wider system of health-care delivery and reports on their particular challenges to promote patient safety during purchasing decisions. Data was collected through observational work, participatory workshops, and semi-structured qualitative interviews, which were analysed and coded. The study takes a systems-based and engineering design approach to the study. Five hospitals took part in this study, and the participants included maintenance, training, clinical end-users, finance, and risk departments. The main stakeholders for purchasing were identified to be staff from clinical engineering (Maintenance), device users (Clinical), device trainers (Training), and clinical governance for analysing

incidents involving devices (Risk). These stakeholders display different characteristics in terms of interpretation of their roles, competencies for selecting devices, awareness and use of resources for purchasing devices, and attitudes toward the purchasing process. The role of "clinical engineering" is seen by these stakeholders to be critical in mediating between training, technical, and financial stakeholders but not always recognised in practice. The findings show that many devices purchasing decisions are tackled in isolation, which is not optimal for decisions requiring knowledge that is currently distributed among different people within different departments. The challenges expressed relate to the broader system of care and equipment management, calling for a more systemic view of purchasing for medical devices.

16. **[The effects of asset specificity on maintenance financial performance: An empirical application of Transaction Cost Theory to the medical device maintenance field (Cruz, Haugan & Rincon, 2014)]:** This work uses multivariate regression analysis to examine the effects of asset specificity on the financial performance of both external and internal governance structures for medical device maintenance and investigates how the financial performance of external governance structures differs depending on whether a hospital is private or public. The hypotheses were tested using information on 764 medical devices and 62 maintenance service providers, resulting in 1403 maintenance transactions. As such, the data sample is significantly larger than those used in previous studies in this area. The results empirically support the core theoretical argument that governance financial performance is influenced by assets specificity.

17. **[A Comparative Study of Medical Equipment Maintenance Cost and Performance for Selected Saudi Hospitals (Altayyar, 2017)]:** Healthcare technology administrators are always held responsible for the poor performance of the medical equipment maintenance team, delay in response to service requests, and extended downtime. Customer satisfaction is just part of the challenges they are facing. The objective of this study is to analyse and compare the cost of medical equipment maintenance, the performance of medical equipment maintenance team in three major hospitals in Saudi Arabia (academic, military, and public). The annual cost of maintenance per medical equipment, workload per 1 FTE (technical employee), downtime, turnaround time, cost of service ratio (COSR), the hourly cost of maintenance, and an acquisition cost per 1 FTE (technical employee) are used in the assessment and analytical comparison. When comparing the cost of service (COSR), turnaround time, and the downtime in the three hospitals, it can be seen that the

academic hospital has the lowest COSR (3.7%), the lowest downtime (1.2 days) and the lowest turnaround time (1.5 days). The other two hospitals (military and public) have relatively higher COSR (6.7 and 5.8 %) respectively and long downtime (29 and 10.7) days respectively. It is clear from this study that hospitals that use a combination of in house, Original Equipment Manufacturer (OEM), an independent service provider (third party) contract tend to have redundancy in technical staff which results in under worked technical staff and consequently unnecessary increased spending on maintenance, and unfortunate maintenance performance, when measured by the annual cost of maintenance of medical equipment, downtime, and turnaround time. This can be seen in the public hospital which has the highest cost of medical equipment maintenance among the three hospitals ($570).

18. [Building a cloud-based data sharing model for the Saudi national registry for implantable medical devices: Results of a readiness assessment (Alshagathrh et al., 2018)]: Implantable medical device registries are increasingly used as a medium to conduct post-marketing surveillance. Little information is available on the development and implementation of implantable biomedical device registries in general and specifically in the Middle East. This study presents the experiences of building an implantable medical device registry in the Kingdom of Saudi Arabia. The work addresses the early experiences of the Saudi Food and Drug Authority in the planning and development of a data sharing model for the implementation of a medical device registry at different host sites within Saudi Arabia explicitly. A readiness assessment was conducted for two years of surveying the readiness of five hospital sites within Saudi Arabia. Over 60 participants in both orthopaedic and cardiology departments participated in the study. The analysis consisted of a detailed review of the readiness assessment data in terms of the overall system and technology used by the hospitals as well as a comparison of the results collected from the readiness assessment survey. The results of the assessment will help identify the challenges in establishing the registry and the implementation needs within each hospital. Hospitals were eager to participate in the assessment. However, many challenges were identified relating to costs, implementation, patient follow-up, data entry, and change management. Ensuring the safety and efficiency of implantable devices is a goal shared by medical practitioners and regulatory bodies. Registries play a significant role in monitoring the effectiveness of these devices. Standard policies, enforced regulations, standards, and information technology infrastructure are needed to achieve this goal. Furthermore, due to differences in hospital technologies and

standards of clinical practice, building a cloud-based registry system through manual data entry was found to be the most appropriate model for implementation at the national level.

19. [Fully Automated Clinical Engineering Technical Management System. Journal of Clinical Engineering (Mobarek et al. 2006)]: This manuscript describes the different phases of developing, implementing, and evaluating a unique fully automated clinical engineering system at the Ministry of Health in Jordan. This cover automating all related technical issues in 29 hospitals, 685 health centres, 332 dental clinics, 348 paediatrics and mother care clinics, and 23 blood banks. Every piece of medical equipment was assigned an identity code that can be recognised through a bar code scanning system, and similarly, all other involved parameters, such as hospitals, personnel, spare parts, workshops, and others, are also coded comprehensively. The system presents a powerful software package designed based on Oracle and implemented using a network covering different locations of the Directorate of Biomedical Engineering (DBE) at the Ministry of Health all over Jordan through Web-based interactive connection. The complete automation system proves to be an invaluable tool to manage, control, and report all different parameters concerning the considered clinical engineering system including all medical equipment at minimum cost and time as compared with international systems. It is also the first comprehensive system that can read and report in both Arabic and English languages. The system was evaluated and found to be reliable, valid, and unique compared with internationally available systems. The DBE with this automated clinical engineering system has the ISO 9000/2000 certification.

20. [Medical equipment classification: method and decision-making support based on paraconsistent annotated logic (Oshiyama et al., 2012)]: As technology evolves, the role of medical equipment in the healthcare system, as well as technology management, become more critical. Although the existence of large databases containing management information is currently common, extracting useful information from them is still difficult. A useful tool for the identification of frequently failing equipment, which increases maintenance cost and downtime, would be the classification according to the corrective maintenance data. Nevertheless, the establishment of classes may create inconsistencies since an item may be close to two classes by the same extent. Paraconsistent logic might help solve this problem, as it allows the existence of inconsistent (contradictory) information without trivialization. In this paper, a methodology for medical equipment classification based on the ABC

analysis of corrective maintenance data is presented and complemented with a paraconsistent annotated logic analysis, which may enable the decision maker to take into consideration alerts created by the identification of inconsistencies and indeterminacies in the classification.

The discussion for the previous studies had shown good academic research papers and practices in medical devices maintenance. But most of them had discussed one or more factors that affect the quality, but none of them had come up with a wide range or a full explanation or designing a decision support system to improve medical devices maintenance in general or for a developing country like Saudi Arabia which this study focus on.

3.5 Summary of the Chapter

Overall, the discussion for the previous chapter is a review for good national Saudi Arabian organisations, international organisations, postgraduate dissertations include master's and PhD thesis, and technical academic papers practices. This had shown rich experience and general guidelines and practices in medical devices maintenance. Even though, most of them had discussed one or more factors that affect the quality but they will help to come up with wide range or a full image explanation or full image of designing a decision support system to improve medical devices maintenance in general and they will help to develop a comprehensive nationwide designing a decision support system to improve medical devices maintenance.

CHAPTER 4: RESEARCH METHODOLOGY

4.1 Introduction

In advance of collecting a general information about the designated sample of study focus on medical devices maintenance activities, it had been decided to choose the Riyadh, the capital city of the Kingdom of Saudi Arabia where is the sample of study take place for two reasons; first, total hospitals in Riyadh are about 100 hospitals about 20% out of 487 hospitals nationwide. Second, In Riyadh, there are different levels of all hospitals types nationwide. Third, it is easy to control the data collection process instead to travel in a vast country with an area of 2.2 million square kilometres.

The methodology of the research used the descriptive approach. A research study classified as a clear study attempts to describe a situation, problem, phenomenon, service or programme systematically, provides information about the living conditions of a community or describes attitudes towards an issue. It attempts to describe the types of service provided by an organisation, the administrative structure of an organisation, or the attitudes of employees towards management. The primary purpose of such studies is to describe what is prevalent concerning the issue or the /problem under study. (Kumar, 2014)

The methodology of the research contains seven main steps:

1- Designing a survey of the clinical engineering department in Saudi Arabia (Appendix-1) that includes an overview of medical devices maintenance in Saudi Arabian hospitals. The survey contains four main parts: General Information - Structure, Personnel, Responsibilities, and Resources.

2- Applying the survey of the clinical engineering department in Saudi Arabia and collected the designated information.

3- Designing a questionnaire of evaluating current management performance for medical devices maintenance in Saudi hospitals (Appendix-2) to identify the parameters that involve in medical devices maintenance in Saudi Arabian hospitals.

4- Validating the questionnaire for consistency and stability.

5- Applying the questionnaire of evaluating current management performance for medical devices maintenance and collected the designated information.

6- Designing the proposed decision support system. (Chapter 6).

7- Validating the proposed decision support system. (Chapter 6).

Statistical analysis methods:

In order to fulfil the study objectives and analysing the collected data, several suitable statistic methods have been used using Statistical Package for Social Sciences (SPSS). After coding and data entry into the computer, specifying the length of Likert scale Quintet cells (maximum and minimum) was used in the study pivots the degree has been calculated (5-1=4). Then, they divided into the scale cells in order to obtain correct cell length, i.e. (4/5=0.80), after that this value has been added to the less value in the scale (or the beginning of scale which is integer one) that is for specifying maximum of this cell, according the length of cells became as the following:

- From 1.00 to 1.80 (Strongly Disagree) towards each statement indifference of the pivot required to be measured.
- From 1.81 to 2.60 represents (Disagree) towards each statement in the difference of the pivot required to be measured.
- From 2.61 to 3.40 represents (Undecided (Neutral) towards each statement in the difference of the pivot required to be measured.
- From 3.41 to 4.20 represents (Agree) towards each statement indifference of the pivot required to be measured.
- From 4.21 to 5.00 represents (Strongly Agree) towards each statement indifference of the pivot required to be measured.

After that, the following statistical measures have been calculated:

1. Frequency (number) & Percentage
2. Weighted Mean
3. Mean
4. Standard Deviation
5. Independent Sample T-test

4.2 Survey of Clinical Engineering Departments

A sample of study:

The survey of clinical engineering departments focused on 23 hospitals in Riyadh, where the research took a place for the following reasons:

1. Total Hospitals in Riyadh are 93 hospitals about 20% out of 487 hospitals nationwide (Ministry of Health, 2016).
2. In Riyadh, there are different levels of all hospital's types nationwide. It is easy to control the data collection process instead to travel across the whole country.

Table 4.1: Sample of study

Sector	Hospitals
Ministry of Health	282
Private	158
Other Governmental Hospitals	47
Total Hospital in KSA	487
Total Hospital in Riyadh	93
Rate	20%

The survey contains four main parts: General Information - Structure, Personnel, Responsibilities, and Resources

Part 1: General Information

1. Hospital type: Teaching hospital - General hospital - Non-Teaching hospital - Specialised hospital
2. Number of hospital heds and number of ICU (intensive-care unit) Beds
3. Approximate value of the Clinical equipment in the hospital (in Saudi Riyals)
4. Approximate budget for new Clinical equipment per year (in Saudi Riyals)
5. Some devices supported by the clinical engineering department and Approx. value of the medical devices under the clinical engineering department (in Saudi Riyals)

Part 2: Structure

1- The Clinical Engineering services function as a separate department, established in (year), or part of another department/unit (please specify)
2- Whom does the department/ unit report to?

3- Are you satisfied with the reporting authority?

4- How much is the allocated space in m^2?

Part 3: Personnel

1. Number of employees, qualifications (the highest degree), average age and years of professional experience (specify the names in each box)
2. How many of the technical staff are women (excluding the clerical staff)?
3. Some clerical staff.
4. How many Clinical engineers are certified Technicians?
5. How many are members of national and international professional associations? Clinical engineers Technicians
6. How often does the clinical engineering department personnel take training courses?

Part 4 Responsibilities

Table 4.2: The distribution of the time of the Department in general

No	What is the distribution of the time of the Department in general, engineers, and technicians	Department in general (%)
1	Administration	
2	Equipment Inventory	
3	Preventive Maintenance (PM)	
4	Corrective Maintenance (CM)	
5	Pre-purchase Consultation:	
6	Acceptance Testing (Incoming Inspections)	
7	Management of Service Contracts	
8	Risk Management	
9	Quality Control	
10	Education and Training	
11	Research and Development	

Part 5 Resources

1. Is the number of personnel adequate? If “No”, please state additional personnel required: Engineers _____Technicians _____
2. Is the provided occupancy area adequate?
3. Is the available test equipment adequate for performing your duties?
4. Is the spare parts inventory adequate?
5. Do you have a computerised system for management of the inventory and the maintenance of the equipment?
6. Do you have a quality assurance program?

7. Do you use a productivity index to measure staff performance?
8. Do you feel that the clinical engineering department in your hospital is well accepted and its work recognised?

4.3 A Questionnaire of Medical Devices Maintenance

In advance of investigating the real situation of medical devices maintenance, the researcher had developed a questionnaire of evaluating current management performance for medical devices maintenance in Saudi hospitals (Appendix-2) to identify the parameters that involve in medical devices maintenance in Saudi Arabian hospitals. After that, the researcher had validated the questionnaire of evaluating current management performance for medical devices maintenance in Saudi Hospitals.

4.3.1 Qualitative Indicators of the Questionnaire

Based on the nine main stages of medical devices maintenance life cycles as follows: 1. Planning 2. Acquisition 3. Delivery and Incoming Inspection 4. Inventory and Documentation 5. Installation, Commissioning, and Acceptance 6. Training of Users and Operators 7. Monitoring of Use and Performance 8. Maintenance 9. Replacement or Disposal, the researcher had contained the folwing qualitative indicators for technical activities for medical devices management as follows:

1- Planning

1. The program administration has a comprehensive written strategic plan for all program activities.
2. The hospital administration supports the strategic plan for the program.
3. The program administration has a comprehensive written medical devices management plan.
4. The program administration implements national laws and regulations for medical devices planning effectively
5. The program administration implements a comprehensive decision-making criterion for medical devices management plan effectively.
6. The program administration implements medical devices management plan effectively

7. The program administration has enough allocating resources to run the program activities effectively.
8. The program administration has adequate qualified staff to run the program activities effectively.
9. The program administration has an adequate operating budget to run the program activities effectively.
10. The program administration improves program plans periodically.

2- Acquisition (evaluation and procurement)

1. The program administration has a comprehensive written policy and procedures for medical devices acquisition
2. The program administration implements national laws and regulations for medical devices acquisition effectively.
3. The program administration implements the procedures for medical devices acquisition effectively
4. The program administration implements a comprehensive computer system for medical devices acquisition procedures effectively
5. The program administration implements the procedures for medical devices needs assessment effectively
6. The program administration implements pre-purchase evaluation and selection procedures effectively
7. The program administration provides operating and service manuals for medical devices.
8. The program administration improves the policy and procedures for medical devices acquisition periodically,

3-Delivery and Incoming Inspection

1. The program administration has a comprehensive written policy and procedures for medical devices delivery and incoming inspection.
2. The program administration implements policy and procedures for medical devices delivery and incoming inspection effectively
3. The program administration implements the procedures for medical devices delivery effectively
4. The program administration implements the procedures for medical devices incoming inspection effectively.

5. The program administration improves policy and procedures for medical devices delivery and incoming inspection periodically.

4-Inventory and Documentation

1. The program administration has a comprehensive written policy and procedures for medical devices inventory and documentation.
2. The program administration implements national laws and regulations for medical devices Inventory and documentation effectively.
3. The program administration implements the procedures for medical devices inventory effectively.
4. The program administration implements the procedures for medical devices documentation effectively
5. The program administration implements a comprehensive computerised maintenance management system (CMMS) effectively
6. The program administration provides enough inventory of spare parts for medical devices
7. The program administration provides enough inventory of accessories for medical devices
8. The program administration improves the policy and procedures for medical devices inventory and documentation periodically.

5-Installation, Commissioning, and Acceptance

1. The program administration has a comprehensive written policy and procedures for medical devices installation, commissioning, and acceptance.
2. The program administration implements national laws and regulations for medical devices installation, commissioning, and acceptance effectively.
3. The program administration implements the procedures for medical devices pre-installation requirements effectively.
4. The program administration implements the procedures for medical devices installation effectively.
5. The program administration implements the procedures for medical devices commissioning effectively.
6. The program administration implements the procedures for medical devices acceptance effectively.

7. The program administration improves the policy and procedures for medical devices installation, commissioning, and acceptance periodically.

6- Training of Users and Operators

1. The program administration has a comprehensive written policy and procedures for medical devices training of users and operators.
2. The program administration implements national laws and regulations for medical devices training of users and operators effectively.
3. The program administration implements the medical devices training procedures for medical staff effectively.
4. The program administration implements the medical devices training procedures for A biomedical engineering/equipment technician/technologist (BMET) effectively.
5. The program administration implements the medical devices training procedures for clinical engineers effectively.
6. The program administration improves the policy and procedures for medical devices training of users and operators periodically.

7-Monitoring of Use and Performance

1. The program administration has a comprehensive written policy and procedures for the medical devices monitoring of use and performance.
2. The program administration implements national laws and regulations for the medical devices monitoring of use and performance effectively.
3. The program administration implements the procedures for the medical devices monitoring of use effectively.
4. The program administration implements the policy and procedures for the medical devices performance effectively.
5. The program administration implements the procedures for the medical device's contracts effectively.
6. The program administration implements the procedures for recall system for the medical devices effectively
7. The program administration improves the policy and procedures for the medical devices monitoring of use and performance periodically.

8-Maintenance (Corrective, preventive)

1. The program administration has a comprehensive written policy and procedures for medical devices maintenance.
2. The program administration implements national laws and regulations for the medical device's maintenance effectively.
3. The program administration implements the procedures of the corrective maintenance for the medical devices effectively.
4. The program administration implements the procedures of the preventive maintenance for the medical devices effectively
5. The program administration provides adequate test equipment for medical devices.
6. The program administration implements the procedures of the calibration of the medical device effectively.
7. The program administration improves the policy and procedures for the medical devices maintenance periodically.

9-Replacement and Disposal

1. The program administration has a comprehensive written policy and procedures for medical devices replacement and disposal.
2. The program administration implements national laws and regulations for the medical device's replacement and disposal effectively
3. The program administration implements the medical devices replacement effectively
4. The program administration implements the medical devices disposal effectively.
5. The program administration improves the policy and procedures for the medical devices replacement and disposal periodically.

4.4 Validating the Questionnaire for Consistency and Stability

4.4.1 Veracity the Internal Consistency of the Questionnaire

After being sure of the apparent veracity for the study tool, the researcher has verified it in the field and on the data of the sample. After that , the researcher calculated Person Correlation Coefficient in order to know the internal veracity for the questionnaire where the correlation coefficient has been calculated between the degree of each questionnaire statements in total degree for the pivot to which the statement belongs as stated in the following tables.

Table 4.3: Person's Correlation Coefficient for First Pivot Statements

Statement No.	The correlation coefficient in the pivot	Statement No.	The correlation coefficient in the pivot
1	**0.895	6	**0.908
2	**0.946	7	**0.847
3	**0.892	8	**0.927
4	**0.914	9	**0.952
5	**0.886	10	**0.957

** significant at a level of 0.01 and less

Table 4.4: Person's Correlation Coefficient for Second Pivot Statements

Statement No.	The correlation coefficient in the pivot	Statement No.	The correlation coefficient in the pivot
1	**0.914	4	**0.958
2	**0.957	6	**0.960
3	**0.958	7	**0.971

** significant at the level of 0.01 and less

Table 4.5: Person's Correlation Coefficient for Third Pivot Statements

Statement No.	The correlation coefficient in the pivot	Statement No.	The correlation coefficient in the pivot
1	**0.922	4	**0.949
2	**0.949	5	**0.951
3	**0.964	-	-

** significant at the level of 0.01 and less

Table 4.6: Coefficient for Fourth Pivot Statements

Statement No.	The correlation coefficient in the pivot	Statement No.	The correlation coefficient in the pivot
1	**0.915	5	**0.958
2	**0.937	6	**0.967
3	**0.940	7	**0.960
4	**0.932	8	**0.957

** significant at the level of 0.01 and less

Table 4.7: Person's Correlation Coefficient for Fifth Pivot Statements

Statement No.	The correlation coefficient in the pivot	Statement No.	The correlation coefficient in the pivot
1	**0.910	4	**0.959
2	**0.958	5	**0.956
3	**0.960	6	**0.974

** significant at the level of 0.01 and less

Table 4.8: Person's Correlation Coefficient for Sixth Pivot Statements

Statement No.	The correlation coefficient in the pivot	Statement No.	The correlation coefficient in the pivot
1	**0.913	4	**0.962
2	**0.952	5	**0.961
3	**0.938	6	**0.969

** significant at the level of 0.01 and less

Table 4.9: Person's Correlation Coefficient for Seventh Pivot Statements

Statement No.	The correlation coefficient in the pivot	Statement No.	The correlation coefficient in the pivot
1	**0.905	5	**0.938
2	**0.950	6	**0.961
3	**0.942	7	**0.949
4	**0.922	8	**0.956

** significant at the level of 0.01 and less

Table 4.10: Person's Correlation Coefficient for Eighth Pivot Statements

Statement No.	The correlation coefficient in the pivot	Statement No.	The correlation coefficient in the pivot
1	**0.882	7	**0.906
2	**0.924	8	**0.908
3	**0.932	9	**0.940
4	**0.938	10	**0.942
5	**0.914	11	**0.952
6	**0.896	-	-

** significant at the level of 0.01 and less

Table 4.11: Person's Correlation Coefficient for Ninth Pivot Statements

Statement No.	The correlation coefficient in the pivot	Statement No.	The correlation coefficient in the pivot
1	**0.905	4	**0.953
2	**0.967	5	**0.967
3	**0.972	-	-

** significant at the level of 0.01 and less

It is clear from tables 4.2- 4.10 that the correlation coefficient value of each statement with its pivot is positive and statistically significant at the level of (0.01) and less the thing that indicates to the veracity of its consistency with its pivots.

4.4.2 Veracity of the Study Tool Stability

To measure the extent of study tool stability (questionnaire) the researcher used (Cronbach's Alpha) in order to be sure of the study tool stability, and table 4.11 explains the coefficients of study tool stability.

Table 4.12: Cronbach's Alpha Coefficient for measuring study tool stability

Axis	Number of statements	Stability
Planning (Assessment of needs, qualifications, resources, support, budget and regulations)	10	0.9775
Acquisition (evaluation and procurement)	6	0.9798
Delivery and Incoming Inspection	5	0.9707
Inventory and Documentation	8	0.9830
Installation, Commissioning, and Acceptance	6	0.9793
Training of Users and Operators	6	0.9779
Monitoring of Use and Performance	8	0.9811
Maintenance (Corrective, preventive)	11	0.9819
Replacement and Disposal	5	0.9738
General stability	65	0.9974

It is clear from table 4.10 that the coefficients of general stability are high where it was reached to (0.9974), and this indicates that the questionnaire enjoys high stability degree which is dependable in field implementation of the study.

4.5 Summary of the Chapter

As a summary of the chapter, a description of the methodology of research with four sections as follows: designing a survey of the clinical engineering department in Saudi Arabia (Appendix-1) that includes an overview of medical devices maintenance in Saudi Arabian hospitals. The survey contains from four main parts: General Information - Structure, Personnel, Responsibilities, and Resources - Designing a questionnaire of evaluating current management performance for medical devices maintenance in Saudi hospitals (Appendix-2) to identify the parameters that involve in medical devices maintenance in Saudi Arabian hospitals - Designing the proposed decision support system. (Chapter 6) - Validating the proposed decision support system. (Chapter 6).

CHAPTER 5: STUDY RESULTS AND ANALYSIS

5.1 Problem Background

A rapid influence of development in technology has affected every aspect of our lives. It has mainly reshaped medical care in the last three decades, and engineering professionals have become intrinsically involved in many efforts. Clinical Engineering departments in Saudi Arabia have emerged with a general objective of assisting in the struggle against disease and disability by providing tools and techniques for research, diagnosis, and treatment.

Most of the maintenance service in the Kingdom runs on a contract basis, and employees change frequently. Thus, it is not possible to find the same experienced trainers all the time. Some of the healthcare facilities have their maintenance teams; Clinical/clinical engineering department is one of these maintenance teams who care for all medical equipment within the facility. Almost all the maintenance staff is -foreigners- non-Saudis. The problem started when the healthcare facilities demand Saudization of such technical job positions. Clinical equipment technicians are one of those positions that required to be fulfilled.

Even though most of the Clinical Engineering Departments in Saudi Arabia apply the US standards, JCI but they are rare in Saudi Arabia, and that would be due to the confusion of medical instrumentation for Clinical engineering departments (engineers and technicians) that exceptionally organised for healthcare facilities within the Saudi Arabia healthcare environments.

This study aims to understand the situation of Saudi Clinical engineering departments, improve and support clinical engineering departments to be involved in repairing and maintaining medical equipment in the healthcare facilities.

5.2 Survey of Clinical Engineering Departments in Saudi Arabia

5.2.1 Introduction

As a proposed study from this research is to get an overview of clinical engineering in Saudi Arabia. This present survey, launched in 2015-16, was performed to identify the

structure, personnel, responsibilities, and resources of the clinical departments in Riyadh, Saudi Arabia and 23 questionnaires were collected from the city, Riyadh.

5.2.2 The Sample of the Study

This study had covered 23 hospitals in Riyadh as follows:

1. King Fahad Medical City
2. Prince Sultan Military Medical City
3. Security Forces Hospital
4. Prince Sultan Heart Centre
5. Yammah Hospital
6. King Saud Medical City
7. Alamal Mental Health Hospital
8. King Saud Chest Hospital
9. King Faisal Specialist Hospital and Research Centre
10. King Khaled Eye Specialist Hospital
11. King Khaled University Hospital
12. King Abdul Aziz University Hospital
13. Riyadh Care Hospital
14. Riyadh Care Hospital
15. Dr. Sulaiman Al Habib Olaya Medical Complex
16. Dr. Abdul Rahman Al-Mishari Hospital
17. Al Hammadi Hospital
18. Al Mobarak Hospital
19. Saudi German Hospital
20. Mouwasat Hospital
21. Obeid Specialized Hospital
22. Dr. Soliman Fakeeh Hospital
23. Al Jafel International Hospital

From these charts and graphs, the results and analysis of these results:

5.2.3 Number of Collected Surveys

Table 5.1: Number of collected surveys based on the hospital type

Public	Private	Teaching	No Teaching	General	Specialist	Total
12	11	2	21	12	11	23

Table 5.2: Collected surveys comparing to the hospital numbers

No of Hospitals	No of Collecting Surveys	Rate
93	23	25%

Number of Collected Surveys is 25%, which reason for the limitation of time and central management process in some hospitals

5.2.4 Study Observations

These are most observations in this study are the following:

1- The average number of hospital beds Vs. the average number of ICU (intensive-care unit) beds:

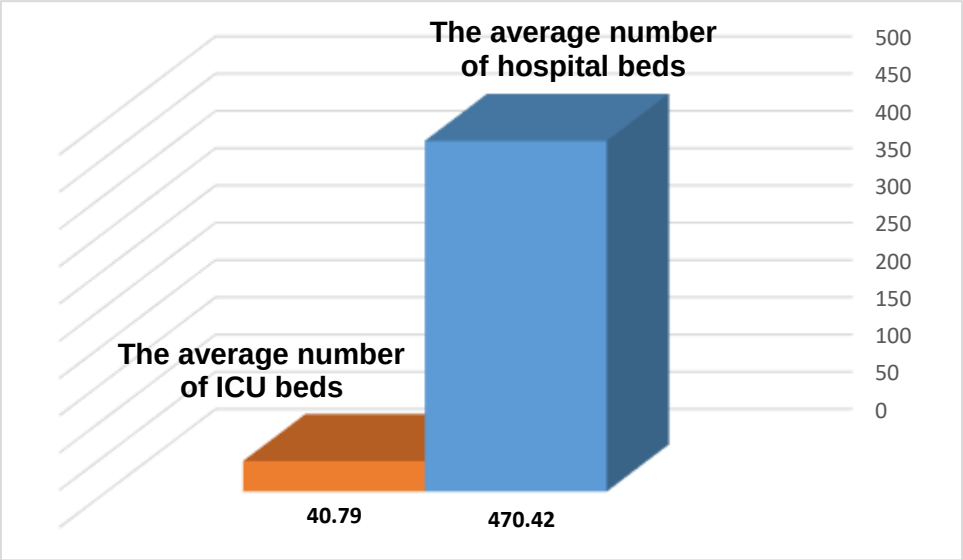


Figure 5.1: Average number of hospital beds Vs. the number of ICU.

In figure 5.1, the average number of hospital beds is 470.42 beds comparing with 40.79 beds number of ICU that shows the significant amount of beds in these hospitals and the big responsibilities for clinical engineering departments.

2- Approximate (replacement) value of the medical devices in the hospital (in US Dollars) and approximate budget for new medical devices per year (in US Dollars):

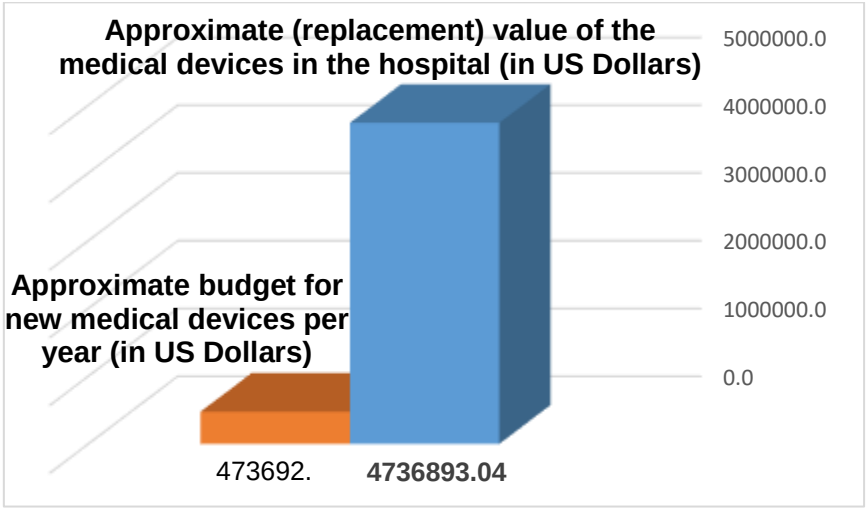


Figure 5.2: Approximate value of the medical devices in the hospital.

In figure 5.2, the average of approximate value of the medical devices in the hospital is $4736893.04 comparing with $473692.43 as an approximate budget for new medical devices per year (in US Dollars) that shows the significant amount of money in these hospitals and the important responsibilities for Clinical engineering departments to plan and manage the medical devices in these hospitals.

3- The Clinical Engineering services function as a separate department or part of another department:

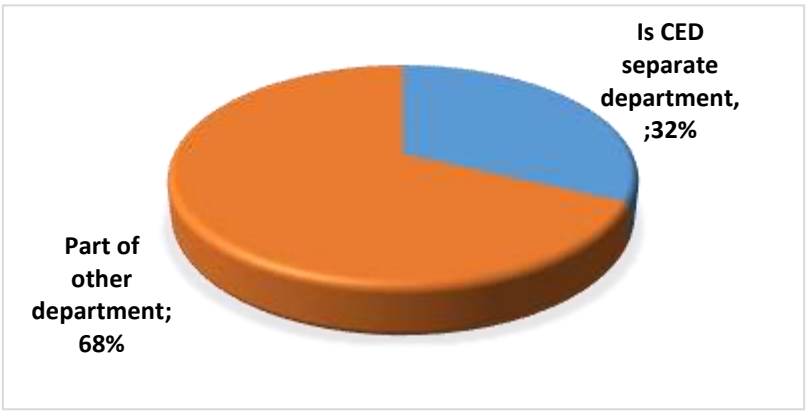


Figure 5.3: The clinical engineering services function.

In figure 5.3, the Clinical engineering services function as a separate department with 32 % comparing with 68% as part of another department, that shows a low amount of

freedom in these hospitals and need to have more sharing of the responsibilities for Clinical engineering departments to plan and manage the medical devices in the hospital.

4- How old are the clinical engineering department?

Clinical engineering departments established in Saudi Arabia hospitals as an average for 18 years in each hospital. This means they are still new in Saudi hospitals but need to have more sharing of the responsibilities to plan and manage the medical devices in the hospital

5- Are you satisfied with the reporting authority?

As a result of the clinical engineering services function as a non-separate department with 63% out of all departments, there 84% of these CED's are confident from the reporting authority. Most of the responses were from departments that exist as separate units. Few answers came from hospitals where the clinical engineering services function as a part of another department.

6- How much is the allocated space in square meters (m^2):

The average of the allocated space in square meters is 150 m^2. Which means they're are quite big enough.

7- Number employees of clinical engineering department:

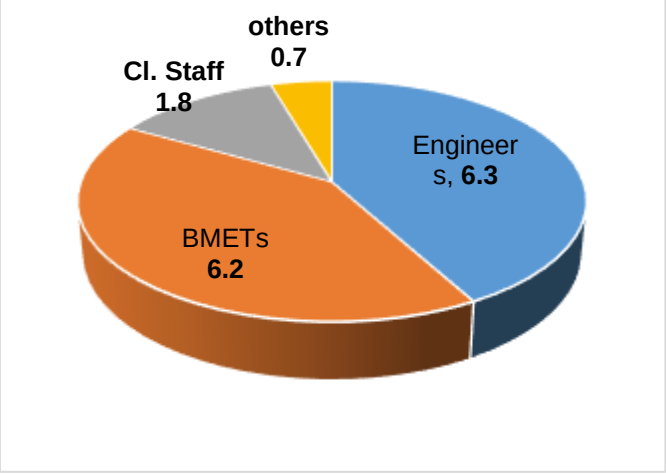


Figure 5.4: Number employees of the clinical engineering department

While the average number of employees of clinical engineering department is about 15 persons, figure 5.3 shows the average number employees of clinical engineering department personnel into four categories: number of engineers is 6.3, number of BMETs is 6.2, number of clerk staff is 1.8 and number of other staff is 0.7. This is a significant number of engineers and BMETs.

8- Average Experience of clinical engineering department Personnel:

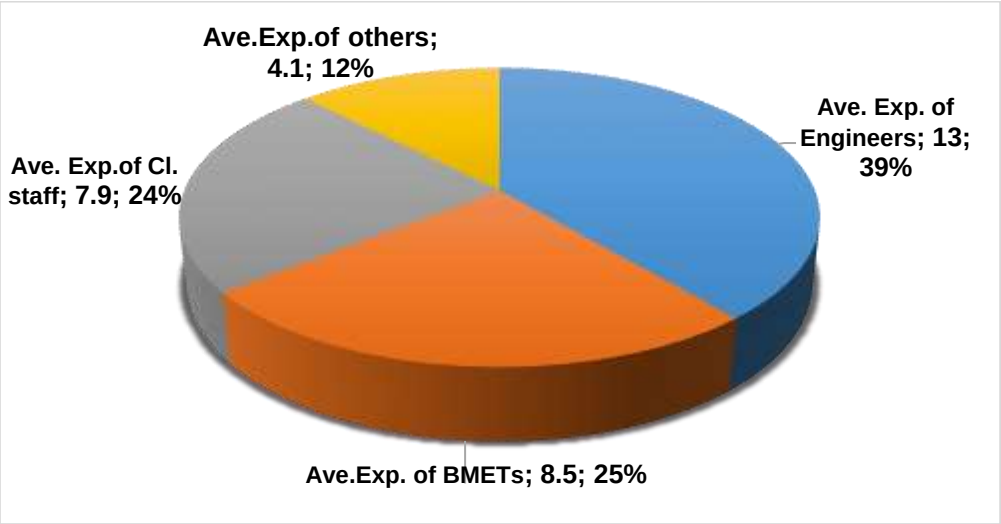


Figure 5.5: The average experience of clinical engineering department personnel.

Figure 5.3 shows the average experience of clinical engineering department personnel: the average experience of Engineers: 13 years, average experience of BMETs: 8.5 years, average experience of Clerk staff 7.9 years, and average experience of others 4.1 years which is quite good.

9- The number of training courses every 24 months

The average number of training courses every 24 months is 1.3 training courses every two years. This is a very low frequency.

10- The number of devices supported by the CED.

The average number of devices supported by the CED is 6873 devices in each hospital. This number is low. In the same time, not all the medical devices are registered in the department database. It is about 80% (5466 medical devices are registered in the department database).

11- Approximate (replacement) value of the medical devices under the CED management (in US million Dollars):

The average of approximate (replacement) value of the medical devices under the CED management is $9,215,800 US Dollars which is quite a significant amount of money.

12- Department activities:

The following table shows the department activities, in general, activates not to compare clinical Engineer with BMETs.

Table 5.3: the average activities of clinical engineering department

Department activities	Average %
1. Administration	3
2. Equipment Inventory	7
3. Preventive Maintenance (PM)	25.3
4. Corrective Maintenance (CM)	28.2
5. Pre-purchase Consultation:	9
6. Acceptance Testing (Incoming Inspections)	6.5
7. Management of Service Contracts	6
8. Risk Management	4
9. Quality Control	4
10. Education and Training	5
11. Research and Development	2
Total	100%

Table 5.3 shows the average activities of the clinical engineering department that displays Preventive Maintenance (PM), and Corrective Maintenance (CM) take most of the CE personnel time which is 53.5%, at the same time other activities have very low in time.

13- Resources

1. The number of personnel adequate?

The average the number of personnel adequate is 39% of their needs.

2. The number of additional engineers required:

The average number of additional required engineers is 2.06 engineers.

3. The number of additional technicians required:

The average number of additional required technicians is 3.56.

4. The provided occupancy area adequate:

The average of participated departments who had responded to the provided occupancy area is adequate about 39% of their needs.

5. Is the available test equipment adequate for performing your duties?

The participated departments had responded to that the available test equipment are adequate for performing their duties are 67% of their needs.

6. Is the spare parts inventory adequate?

The average of participated departments had responded that the available test equipment is adequate for performing their duties are 94% of their needs.

7. Do you have a computerised system for management of the inventory and the maintenance of the equipment?

The average of participated departments who had responded that they have a computerised system for management of the inventory and the maintenance of the equipment are 94%.

8. Do you have a quality assurance program?

The average of participated departments who had responded that they have a quality assurance program are 39%.

9. Do you use a productivity index to measure staff performance?

The average of participated departments had responded that they use a productivity index to measure staff performance are 83%.

10. Do you feel that the clinical engineering department in your hospital is well accepted and its work recognised?

The average of participated departments who had responded that they feel that the clinical engineering department in their hospital is well accepted and its work recognised are 94%.

Conclusions and recommendations:

This result of the survey of Clinical Engineering Departments in Saudi Arabia gives a general overview of the Clinical engineering departments in 23 hospitals in Riyadh, they are about 25% out of all hospital 93 in the capital. Overall, this study is giving a general overview of clinical engineering departments, and the result of the survey had shown some positive activities, and others need to improve. Also, more efforts are needed to gather more information because it is not easy to get access for all these information because they might be not available or not accessible.

5.3 The Questionnaire: Results Analysis

5.3.1 Results Related to Study Individual's Description

1- Distribution of study individuals according to hospital type

In questionnaire, the hospital type has three different categories; Type-1: general / specialised/ medical city, Type-2: governmental/private hospital and Type-3: teaching/ non-teaching hospital. Here is the full result for Distribution of study individuals according to hospital type:

Distribution of study individuals according to hospital type-1:

Table 5.4: Distribution of study individuals according to hospital type-1

Hospital type-1	Number	Percentage
General	107	53.5
Medical city	35	17.5
Specialised	27	13.5
Medical Centre	21	10.5
Missing	10	5.0
Total	200	%100

It is clear from table 5.4, the total number of (107) of the study individuals representing 53.5% of total study individuals are from a general hospital, whereas (35) individuals of them representing 17.5% of total study individuals are from a medical city, against (27) of them representing 13.5% of total study individuals are from a specialised Hospital, whereas (21) of them representing 10.5% of total study individuals are from a medical Centre.

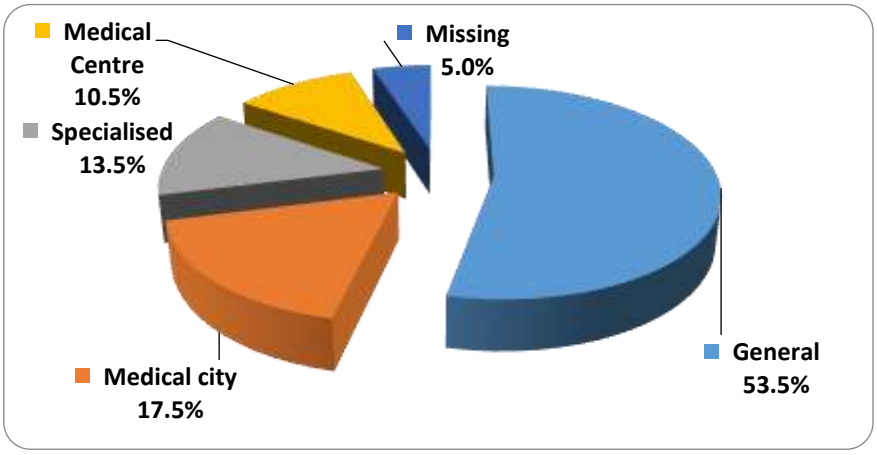


Figure 5.6: Distribution of study individuals according to hospital type-1

Distribution of study individuals according to hospital type-2

Table 5.5: Distribution of study individuals according to hospital type-2

Hospital type	Number	Percentage
Governmental	143	71.5
Private	34	17.0
Missing	23	11.5
Total	200	%100

It is clear from table 5.5, the total number of (143) of the study individuals representing 71.5% of total study individuals the Hospital type is Governmental**,** whereas (34) of them representing 17.0% of total study individuals the Hospital type is Private.

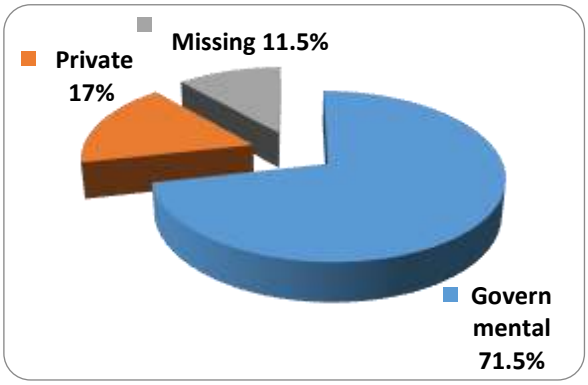


Figure 5.7: Distribution of study individuals according to hospital type-2

Distribution of study individuals according to hospital type-3

Table 5.6: Distribution of study individuals according to hospital type-3

Hospital type	Number	Percentage
Teaching	26	13.0
Non-Teaching	138	69.0
Missing	36	18.0
Total	200	%100

It is clear from table 5.7, the total number of (138) of the study individuals representing 69.0% of total study individuals the Hospital type is Non-Teaching, whereas (26) of them representing 13.0% of total study individuals are from a teaching hospital.

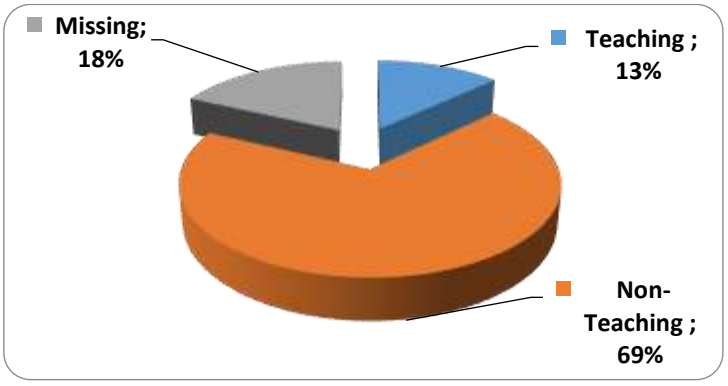


Figure 5.8: Distribution of study individuals according to hospital type-3

Distribution of study individuals according to Position

Table 5.7: Distribution of study individuals according to Position

Position	Number	Percentage
1- Director (general manager)	10	5.0
2- Deputy Director	9	4.5
3- Supervisor	12	6.0
4- Doctor	15	7.5
5- Doctor assistant	15	7.5
6- Nurse	20	10.0
7- Special Technician	22	11.0
8- BMET technician	30	15.0
9- Clinical Engineer	29	14.5
10- Hospital engineer	13	6.5
11- Administration staff	25	12.5
12- Total	200	%100

It is clear from table 5.7, the distribution of study individuals according to position shows the following: 15.0% are BMET technicians, 14.5% are Clinical Engineers, 12.5% are administration staff and 11.0% are special technicians. 10.0% are nurses, 7.5% are doctors, 7.5% are doctor assistants. Whereas 6.5% are hospital engineers, 6.0% are supervisors, 5.0% are directors or general managers, and 4.5% are deputy directors .

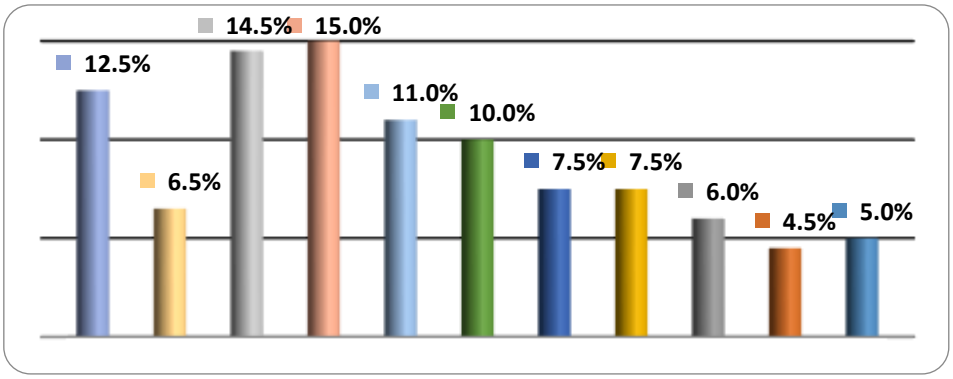


Figure 5.9: Distribution of study individuals according to the position

Distribution of study individuals according to qualification

Table 5.8: Distribution of study individuals according to qualification

Qualification	Number	Percentage
PhD	9	4.5
MSc	49	24.5
BSc	71	35.5
Health /Technical College (Diploma(	52	26.0
High School	19	9.5
Total	200	%100

From table 5.8, the distribution of the study individuals according to position shows the following: 35.5% are BSc , 26.0% are health /technical college gradustes, while 24.5% are MScs. Also, 9.5% are high school, 4.5% are PhDs.

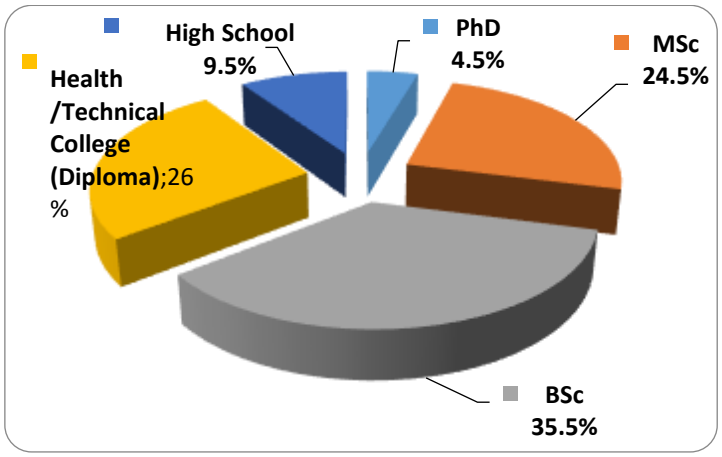


Figure 5.10: Distribution of study individuals according to the qualification

Distribution of study individuals according to the average of experience

Table 5.9: Distribution of study individuals according to average experience

Average of experience	Number	Percentage
0-5 years	29	14.5
6-10 years	69	34.5
11-15 years	65	32.5
15 years and more	37	18.5
Total	200	%100

It is clear from table 5.9, the total number of (69) of the study individuals representing 34.5% of total study individuals the Average of experience is 6-10 years, whereas (65) of them representing 32.5% of total study individuals the Average of expertise is 11-15 years, against (37) of them representing 18.5% of total study individuals the Average of experience is 15 years and more, whereas (29) of them representing 14.5% of total study individuals the Average of experience is 0-5 years.

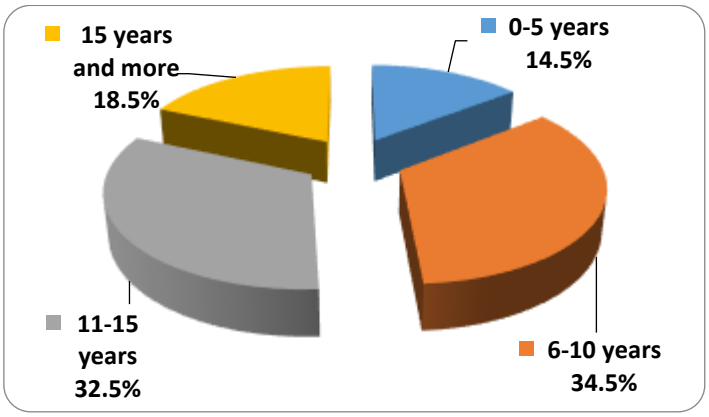


Figure 5.11: Distribution of study individuals according to the average of experience

5.3.2 Results Related to Technical Activities

1- Planning

Table 5.10: Responses for planning:

No	Item	No / Percentage	Strongly Agree	Agree	Undecided (Neutral	Disagree	Strongly Disagree	mean	Std. deviation	serial
1	The department (program) administration has a comprehensive written strategic plan for all department (program) activities	No	14	58	18	55	55	2.61	1.341	1
		%	7.0	29.0	9.0	27.5	27.5			
7	The department (program) administration has enough allocating resources to run the department (program) activities effectively	No.	15	25	67	51	42	2.60	1.169	2
		%	7.5	12.5	33.5	25.5	21.0			
5	The department (program) administration implements a comprehensive decision-making criterion for medical devices management plan effectively	No.	12	36	55	52	45	2.59	1.191	3
		%	6.0	18.0	27.5	26.0	22.5			
3	The department (program) administration has a comprehensive written medical devices management plan	No.	15	42	34	62	47	2.58	1.262	4
		%	7.5	21.0	17.0	31.0	23.5			
6	The department (program) administration implements medical devices management plan effectively	No.	13	31	50	60	46	2.53	1.190	5
		%	6.5	15.5	25.0	30.0	23.0			
4	The department (program) administration implements national laws and regulations for medical devices planning effectively	No.	13	29	48	61	49	2.48	1.194	6
		%	6.5	14.5	24.0	30.5	24.5			
2	The hospital administration supports the strategic plan for the department (program).	No.	16	40	24	62	58	2.47	1.311	7
		%	8.0	20.0	12.0	31.0	29.0			
8	The department (program) administration has adequate qualified staff to run the	No.	13	35	34	63	55	2.44	1.243	8
		%	6.5	17.5	17.0	31.5	27.5			

No	Item	No	degree of approval					mean	Std. deviation	serial
		Percentage	Strongly Agree	Agree	Undecided (Neutral	Disagree	Strongly Disagree			
	department (program) activities effectively									
10	The department (program) administration improves department (program) plans periodically	No.	15	34	27	66	58	2.41	1.273	9
		%	7.5	17.0	13.5	33.0	29.0			
9	The department (program) administration has adequate operating budget to run the department (program) activities effectively	No.	14	35	24	70	57	2.40	1.260	10
		%	7.0	17.5	12.0	35.0	28.5			
Mean								2.51	1.135	

Through the above-stated results, the study individuals disagree on Planning in an average of (2.51 out of 5.00).

It is clear from the results, the study sample individuals are Undecided (Neutral) on the statements No. (1) which is “The department (program) administration has a comprehensive written strategic plan for all department (program) activities” in an average of (2.61 out of 5).

Moreover, it is also clear from the results that the study sample individuals disagree on average on nine statements:

1. Statement No. (7) which is “The department (program) administration has enough allocating resources to run the department (program) activities effectively” in an average of (2.60 out of 5).
2. Statement No. (5) which is “The department (program) administration implements a comprehensive decision-making criterion for medical devices management plan effectively” in an average of (2.59 out of 5).
3. Statement No. (3) which is “The department (program) administration has a comprehensive written medical devices management plan” in an average of (2.58 out of 5).
4. Statement No. (6) which is “The department (program) administration implements medical devices management plan effectively” in an average of (2.53 out of 5).

5. Statement No. (4) which is “The department (program) administration implements national laws and regulations for medical devices planning effectively” in an average of (2.48 out of 5).
6. Statement No. (2) which is “The hospital administration supports the strategic plan for the department (program).” in an average of (2.47 out of 5).
7. Statement No. (8) which is “The department (program) administration has the adequate qualified staff to run the department (program) activities effectively.” in an average of (2.44 out of 5).
8. Statement No. (10) which is “The department (program) administration improves department (program) plans periodically.” in an average of (2.41 out of 5).
9. Statement No. (9) which is “The department (program) administration has the adequate operating budget to run the department (program) activities effectively.” in an average of (2.40 out of 5).

2- Acquisition (evaluation and procurement)

Table 5.11: Responses for acquisition

No.	Item	No.	the degree of approval					mean	Std. Deviation	serial
		%	Strongly Agree	Agree	Undecided (Neutral	Disagree	Strongly Disagree			
1	The department administration has a comprehensive written policy and procedures for medical devices acquisition	No.	16	49	22	58	55	2.56	1.332	1
		%	8.0	24.5	11.0	29.0	27.5			
6	The department administration implements pre-purchase evaluation and selection procedures effectively	No.	15	33	29	68	55	2.43	1.258	2
		%	7.5	16.5	14.5	34.0	27.5			
2	The department administration implements national laws and regulations for medical devices acquisition effectively	No.	15	34	23	71	57	2.40	1.268	3
		%	7.5	17.0	11.5	35.5	28.5			
4	The department administration implements a comprehensive computer system for medical devices acquisition procedures effectively	No.	13	32	32	65	58	2.39	1.239	4
		%	6.5	16.0	16.0	32.5	29.0			
7	The department (program) administration improves the policy and procedures for medical devices acquisition periodically	No.	14	35	23	71	57	2.39	1.259	5
		%	7.0	17.5	11.5	35.5	28.5			

No.	Item	No.	the degree of approval					mean	Std. Deviation	serial
		%	Strongly Agree	Agree	Undecided (Neutral	Disagree	Strongly Disagree			
3	The department (program) administration implements the procedures for medical devices acquisition effectively	No.	14	32	25	68	61	2.35	1.259	6
		%	7.0	16.0	12.5	34.0	30.5			
Mean								2.42	1.210	

Through the above-stated results, the study individuals disagree on the Planning (Acquisition (evaluation and procurement) in an average of (2.42 out of 5.00).

Moreover, it is also clear from the results that the study sample individuals disagree on average on nine statements:

1. Statement No. (1) which is “The department (program) administration has a comprehensive written policy and procedures for medical devices acquisition” in an average of (2.56 out of 5).
2. Statement No. (6) which is “The department (program) administration implements pre-purchase evaluation and selection procedures effectively” in an average of (2.43 out of 5).
3. Statement No. (2) which is “The department (program) administration implements national laws and regulations for medical devices acquisition effectively” in an average of (2.40 out of 5).
4. Statement No. (4) which is “The department (program) administration implements a comprehensive computer system for medical devices acquisition procedures effectively” in an average of (2.39 out of 5).
5. Statement No. (7) which is “The department (program) administration improves the policy and procedures for medical devices acquisition periodically” in an average of (2.39 out of 5).
6. Statement No. (3) which is “The department (program) administration implements the procedures for medical devices acquisition effectively” in an average of (2.35 out of 5).

3- Delivery and Incoming Inspection

Table 5.12: Responses for Delivery and Incoming Inspection

No.	Item	No.	degree of approval					mean	St. Deviation	serial
		%	Strongly Agree	Agree	Undecided (Neutral	Disagree	Strongly Disagree			
1	The department (program) administration has a comprehensive written policy and procedures for medical device delivery and incoming inspection	No.	18	47	20	57	58	2.55	1.359	1
		%	9.0	23.5	10.0	28.5	29.0			
4	The department (program) administration implements the procedures for medical devices incoming inspection effectively	No.	16	34	30	67	53	2.47	1.268	2
		%	8.0	17.0	15.0	33.5	26.5			
2	The department (program) administration implements national laws and regulations for medical devices planning effectively	No.	16	33	29	67	55	2.44	1.271	3
		%	8.0	16.5	14.5	33.5	27.5			
3	The department (program) administration implements the procedures for medical devices delivery effectively	No.	16	35	23	67	59	2.41	1.292	4
		%	8.0	17.5	11.5	33.5	29.5			
5	The department (program) administration improves policy and procedures for medical device delivery and incoming inspection periodically	No.	14	33	22	74	57	2.36	1.249	5
		%	7.0	16.5	11.0	37.0	28.5			
Mean								2.45	1.219	

Through the above-stated results, the study individuals disagree with the Planning (Delivery and Incoming Inspection**)** in an average of (2.45 out of 5.00).

Moreover, it is also clear from the results that the study sample individuals disagree on average on nine statements:

1. Statement No. (1) which is “The department (program) administration has a comprehensive written policy and procedures for medical device delivery and incoming inspection” in an average of (2.55 out of 5).

2. Statement No. (4) which is “The department (program) administration implements the procedures for medical devices incoming inspection effectively” in an average of (2.47 out of 5).

3. Statement No. (2) which is “The department (program) administration implements national laws and regulations for medical devices planning effectively” in an average of (2.44 out of 5).

4. Statement No. (3) which is “The department (program) administration implements the procedures for medical device delivery effectively” in an average of (2.41 out of 5).

5. Statement No. (5) which is “The department (program) administration improves policy and procedures for medical device delivery and incoming inspection periodically” in an average of (2.36 out of 5).

4- Inventory and Documentation

Table 5.13: Responses for Inventory and Documentation

No.	Item	No.	degree of approval					mean	Std. Deviation	serial
		%	Str. Agree	Agree	Und. (Neutral	Disagree	Str. Disagree			
4	The department (program) administration implements the procedures for medical devices documentation effectively	No.	14	31	54	52	49	2.55	1.215	1
		%	7.0	15.5	27.0	26.0	24.5			
1	The department (program) administration has a comprehensive written policy and procedures for medical devices inventory and documentation	No.	16	47	21	59	57	2.53	1.333	2
		%	8.0	23.5	10.5	29.5	28.5			
5	The department (program) administration implements a comprehensive computerised maintenance management system (CMMS)effectively	No.	15	34	32	64	55	2.45	1.263	3
		%	7.5	17.0	16.0	32.0	27.5			
2	The department (program) administration implements national laws and regulations for medical devices Inventory and documentation effectively	No.	16	30	29	69	56	2.41	1.261	4
		%	8.0	15.0	14.5	34.5	28.0			
6	The department (program) administration provides enough inventory of spare parts for medical devices	No.	14	39	21	67	59	2.41	1.285	5
		%	7.0	19.5	10.5	33.5	29.5			

No.	Item	No.	degree of approval					mean	Std. Deviation	serial
		%	Str. Agree	Agree	Und. (Neutral	Disagree	Str. Disagree			
3	The department (program) administration implements the procedures for medical devices inventory effectively	No.	14	34	27	69	56	2.40	1.252	6
		%	7.0	17.0	13.5	34.5	28.0			
7	The department (program) administration provides enough inventory of accessories for medical devices	No.	15	33	23	75	54	2.40	1.252	7
		%	7.5	16.5	11.5	37.5	27.0			
8	The department (program) administration improves the policy and procedures for medical devices inventory and documentation periodically	No.	14	34	23	71	58	2.38	1.258	8
		%	7.0	17.0	11.5	35.5	29.0			
Mean								2.44	1.196	

Through the above-stated results, the study individuals disagree with the Planning (Inventory and Documentation) in an average of (2.44 out of 5.00).

Moreover, it is also clear from the results that the study sample individuals disagree on average on nine statements:

1. Statement No. (4) which is “The department (program) administration implements the procedures for medical device documentation effectively” in an average of (2.55 out of 5).
2. Statement No. (1) which is “The department (program) administration has a comprehensive written policy and procedures for medical devices inventory and documentation” in an average of (2.53 out of 5).
3. Statement No. (5) which is “The department (program) administration implements a comprehensive computerised maintenance management system (CMMS) effectively” in an average of (2.45 out of 5).
4. Statement No. (2) which is “The department (program) administration implements national laws and regulations for medical device inventory and documentation effectively” in an average of (2.41 out of 5).
5. Statement No. (6) which is “The department (program) administration provides enough inventory of spare parts for medical devices” in an average of (2.41 out of 5).

6. Statement No. (3) which is “The department administration implements the procedures for medical devices inventory effectively” in an average of (2.40 out of 5).
7. Statement No. (7) which is “The department (program) administration provides enough inventory of accessories for medical devices” in an average of (2.40 out of 5).
8. Statement No. (7) which is “The department (program) administration improves the policy and procedures for medical devices inventory and documentation periodically” in an average of (2.38 out of 5).

5- Installation, Commissioning, and Acceptance

Table 5.14: Responses for Installation, Commissioning, and Acceptance

No.	Item	No.	degree of approval					mean	Std. Dev	serial
		%	S. Agree	Agree	Und. (Neutral	Disagree	S. Disagree			
1	The department administration has a comprehensive written policy and procedures for medical device installation, commissioning, and acceptance	No.	18	50	20	58	54	2.60	1.352	1
		%	9.0	25.0	10.0	29.0	27.0			
2	The department administration implements national laws and regulations for medical devices installation, commissioning, and acceptance effectively	No.	16	35	22	68	59	2.40	1.292	2
		%	8.0	17.5	11.0	34.0	29.5			
3	The department administration implements the procedures for medical devices pre-installation requirements effectively	No.	14	33	26	70	57	2.38	1.251	3
		%	7.0	16.5	13.0	35.0	28.5			
5	The department (program) administration implements the procedures for medical devices acceptance effectively	No.	16	31	23	71	59	2.37	1.273	4
		%	8.0	15.5	11.5	35.5	29.5			
4	The department (program) administration implements the procedures for medical devices installation effectively	No.	14	31	26	72	57	2.36	1.241	5
		%	7.0	15.5	13.0	36.0	28.5			
6	The department administration improves the policy and procedures for medical device installation, commissioning, and acceptance periodically	No.	14	30	22	74	60	2.32	1.243	6
		%	7.0	15.0	11.0	37.0	30.0			
Mean								2.41	1.215	

Through the above-stated results, the study individuals disagree with the Planning (Installation, Commissioning, and Acceptance) in an average of (2.41 out of 5.00).

Moreover, it is also clear from the results that the study sample individuals disagree on average on nine statements:

9. Statement No. (1) which is “The department (program) administration has a comprehensive written policy and procedures for medical device installation, commissioning, and acceptance” in an average of (2.60 out of 5).
10. Statement No. (2) which is “The department (program) administration implements national laws and regulations for medical device installation, commissioning, and acceptance effectively” in an average of (2.40 out of 5).
11. Statement No. (3) which is “The department (program) administration implements the procedures for medical devices-installation requirements effectively” in an average of (2.38 out of 5).
12. Statement No. (5) which is “The department (program) administration implements the procedures for medical devices acceptance effectively” in an average of (2.37 out of 5).
13. Statement No. (4) which is “The department (program) administration implements the procedures for medical device installation effectively” in an average of (2.36 out of 5).
14. Statement No. (6) which is “The department (program) administration improves the policy and procedures for medical device installation, commissioning, and acceptance periodically” in an average of (2.32 out of 5).

6- Training of Users and Operators

Table 5.15: Responses for Training of Users and Operators

No.	Item	No.	the degree of approval					mean	Std. Dev.	serial
		%	S. Agree	Agree	Und. (Neutral	Disagree	S. Disagree			
1	The department administration has a comprehensive written policy and procedures for medical devices training of users and operators	No.	15	46	20	64	55	2.51	1.311	1
		%	7.5	23.0	10.0	32.0	27.5			

5	The department (program) administration implements the medical devices training procedures for clinical engineers effectively	No.	15	36	23	70	56	2.42	1.273	2
		%	7.5	18.0	11.5	35.0	28.0			
2	The department (program) administration implements national laws and regulations for medical devices training of users and operators effectively	No.	15	36	23	69	57	2.42	1.277	3
		%	7.5	18.0	11.5	34.5	28.5			
4	The department (program) administration implements the medical devices training procedures for BMET effectively	No.	15	30	32	66	57	2.40	1.252	4
		%	7.5	15.0	16.0	33.0	28.5			
6	The department (program) administration improves the policy and procedures for medical devices training of users and operators periodically	No.	15	34	23	69	59	2.38	1.275	5
		%	7.5	17.0	11.5	34.5	29.5			
3	The department (program) administration implements the medical devices training procedures for medical staff effectively	No.	14	29	29	71	57	2.36	1.232	6
		%	7.0	14.5	14.5	35.5	28.5			
Mean								2.42	1.205	

Through the above-stated results, the study individuals disagree on the planning (Training of Users and Operators) in an average of (2.42 out of 5.00).

Also, it is also clear from the results that the study sample individuals disagree on average on nine statements:

1. Statement No. (1) which is “The department (program) administration has a comprehensive written policy and procedures for medical devices training of users and operators “in an average of (2.51 out of 5).
2. Statement No. (5) which is “The department (program) administration implements the medical devices training procedures for clinical engineers effectively “in an average of (2.42 out of 5).
3. Statement No. (2) which is “The department (program) administration implements national laws and regulations for medical devices training of users and operators effectively “in an average of (2.42 out of 5).

4. Statement No. (4) which is “The department (program) administration implements the medical devices training procedures for BMET effectively” in an average of (2.40 out of 5).

5. Statement No. (6) which is “The department (program) administration improves the policy and procedures for medical devices training of users and operators periodically “in an average of (2.38 out of 5).

6. Statement No. (3) which is “The department (program) administration implements the medical devices training procedures for medical staff effectively” in an average of (2.36 out of 5).

7- Monitoring of Use and Performance

Table 5.16: Responses for Monitoring of Use and Performance

No	Item	No.	degree of approval					mean	S. Dev.	serial
		%	Strongly Agree	Agree	Un. (Neutral	Disagree	S. Disagree			
1	The department (program) administration has a comprehensive written policy and procedures for the medical devices monitoring of use and performance	No.	16	49	27	54	54	2.59	1.327	1
		%	8.0	24.5	13.5	27.0	27.0			
4	The department (program) administration implements the procedures for monitoring medical devices safety effectively	No.	11	30	52	57	50	2.48	1.177	2
		%	5.5	15.0	26.0	28.5	25.0			
7	The department (program) administration implements the procedures for recall system for the medical devices with the National Centre for Medical Devices Reporting effectively	No.	18	34	27	65	56	2.47	1.303	3
		%	9.0	17.0	13.5	32.5	28.0			
5	The department (program) administration implements the policy and procedures for the medical devices performance effectively	No.	12	35	40	59	54	2.46	1.227	4
		%	6.0	17.5	20.0	29.5	27.0			
3	The department (program) administration implements the procedures for the medical	No.	15	31	32	66	56	2.42	1.253	5
		%	7.5	15.5	16.0	33.0	28.0			

No	Item	No.	degree of approval					mean	S. Dev.	serial
		%	Strongly Agree	Agree	Un. (Neutral	Disagree	S. Disagree			
	devices monitoring of use effectively									
2	The department (program) administration implements national laws and regulations for the medical devices monitoring of use and performance effectively	No.	14	36	26	65	59	2.41	1.272	6
		%	7.0	18.0	13.0	32.5	29.5			
6	The department (program) administration implements the procedures for the medical device's contracts management effectively	No.	15	32	30	64	59	2.40	1.268	7
		%	7.5	16.0	15.0	32.0	29.5			
8	The department (program) administration improves the policy and procedures for the medical devices monitoring of use and performance periodically	No.	14	33	25	68	60	2.36	1.261	8
		%	7.0	16.5	12.5	34.0	30.0			
Mean								2.45	1.186	

Through the above-stated results, the study individuals disagree on the Planning (Monitoring of Use and Performance) in an average of (2.45 out of 5.00).

Moreover, it is also clear from the results that the study sample individuals disagree on average on nine statements:

1. Statement No. (1) which is "The department (program) administration has a comprehensive written policy and procedures for the medical devices monitoring of use and performance" in an average of (2.59 out of 5).
2. Statement No. (4) which is "The department (program) administration implements the procedures for monitoring medical devices safety effectively" in an average of (2.48 out of 5).
3. Statement No. (7) which is "The department (program) administration implements the procedures for recall system for the medical devices with National Centre for Medical Devices Reporting effectively" in an average of (2.47 out of 5).

4. Statement No. (5) which is “The department (program) administration implements the policy and procedures for the medical devices performance effectively” in an average of (2.46 out of 5).
5. Statement No. (3) which is “The department (program) administration implements the procedures for the medical devices monitoring of use effectively” in an average of (2.42 out of 5).
6. Statement No. (2) which is “The department (program) administration implements national laws and regulations for the medical devices monitoring of use and performance effectively” in an average of (2.41 out of 5).
7. Statement No. (6) which is “The department (program) administration implements the procedures for the medical devices contracts management effectively” in an average of (2.40 out of 5).
8. Statement No. (8) which is “The department (program) administration improves the policy and procedures for the medical devices monitoring of use and performance periodically” in an average of (2.36 out of 5).

8- Maintenance (Corrective, preventive)

Table 5.17: Responses for Maintenance (Corrective, preventive**)**

No	Item	No.	degree of approval					mean	Deviation	serial
		%	St. Agree	Agree	Und. (Neutral)	Disagree	St. Disagree			
1	The department (program) administration has a comprehensive written policy and procedures for the medical devices maintenance	No.	21	47	22	56	54	2.62	1.373	1
		%	10.5	23.5	11.0	28.0	27.0			
5	The department (program) administration provides adequate space for the workshop for medical devices maintenance	No.	12	34	52	54	48	2.54	1.198	2
		%	6.0	17.0	26.0	27.0	24.0			
4	The department (program) administration implements the procedures of the preventive maintenance for	No.	13	23	59	55	50	2.47	1.173	3
		%	6.5	11.5	29.5	27.5	25.0			

No	Item	No.	degree of approval					mean	Deviation	serial
		%	St. Agree	Agree	Und. (Neutral)	Disagree	St. Disagree			
	the medical devices effectively									
8	The department (program) administration provides appropriate tools and equipment for medical devices maintenance	No.	12	25	61	49	53	2.47	1.182	4
		%	6.0	12.5	30.5	24.5	26.5			
9	The department (program) administration provides adequate appropriate test and measurement equipment for medical devices maintenance	No.	16	31	32	65	56	2.43	1.266	5
		%	8.0	15.5	16.0	32.5	28.0			
7	The department (program) administration provides adequate spare parts for medical devices	No.	12	22	54	61	51	2.42	1.157	6
		%	6.0	11.0	27.0	30.5	25.5			
6	The department (program) administration provides operating and service manuals for medical devices	No.	13	25	46	65	51	2.42	1.183	7
		%	6.5	12.5	23.0	32.5	25.5			
3	The department (program) administration implements the procedures of the corrective maintenance for the medical devices effectively	No.	14	32	34	64	56	2.42	1.246	8
		%	7.0	16.0	17.0	32.0	28.0			
10	The department (program) administration calibrates the test and measurement equipment periodically	No.	16	31	26	70	57	2.40	1.268	9
		%	8.0	15.5	13.0	35.0	28.5			
2	The department (program) administration implements national laws and regulations for the medical devices maintenance effectively	No.	12	32	30	66	60	2.35	1.231	10
		%	6.0	16.0	15.0	33.0	30.0			
11	The department (program) administration improves the policy and procedures for the medical devices maintenance periodically	No.	14	28	28	69	61	2.33	1.240	11
		%	7.0	14.0	14.0	34.5	30.5			
Mean								2.44	1.132	

Through the above-stated results, the study individuals disagree with the Planning (Maintenance (Corrective, preventive)) in an average of (2.44 out of 5.00). Moreover, it is also clear from the results that the study sample individuals are Undecided (Neutral) **on** average on one statement:

1. Statement No. (1) which is “The department (program) administration has a comprehensive written policy and procedures for the medical devices maintenance” in an average of (2.62 out of 5).

Moreover, it is also clear from the results that the study sample individuals disagree on average on nine statements:

1. Statement No. (5) which is “The department (program) administration provides adequate space for the workshop for medical devices maintenance” in an average of (2.54 out of 5).
2. Statement No. (4) which is “The department (program) administration implements the procedures of the preventive maintenance for the medical devices effectively” in an average of (2.47 out of 5).
3. Statement No. (8) which is “The department (program) administration provides appropriate tools and equipment for medical devices maintenance” in an average of (2.47 out of 5).
4. Statement No. (9) which is “The department (program) administration provides adequate, appropriate test and measurement equipment for medical devices maintenance” in an average of (2.43 out of 5).
5. Statement No. (7) which is “The department (program) administration provides adequate spare parts for medical devices” in an average of (2.42 out of 5).
6. Statement No. (6) which is “The department (program) administration provides operating and service manuals for medical devices” in an average of (2.42 out of 5).
7. Statement No. (3) which is “The department (program) administration implements the procedures of the corrective maintenance for the medical devices effectively” in an average of (2.42 out of 5).
8. Statement No. (10) which is “The department (program) administration calibrates the test and measurement equipment periodically” in an average of (2.40 out of 5).
9. Statement No. (2) which is “The department (program) administration implements national laws and regulations for the medical devices maintenance effectively” in an average of (2.35 out of 5).

10. Statement No. (11) which is “The department (program) administration improves the policy and procedures for the medical devices maintenance periodically” in an average of (2.33 out of 5).

9- Replacement and Disposal

Table 5.18: Responses for Replacement and Disposal

No	Item	No.	degree of approval					mean	Std. Devi	serial
		%	St. Agree	Agree	Undecided (Neutral)	Disagree	Strongly Disagree			
1	The department administration has a comprehensive written policy and procedures for the medical devices replacement and disposal	No.	19	44	23	58	56	2.56	1.351	1
		%	9.5	22.0	11.5	29.0	28.0			
4	The department administration implements the medical devices disposal effectively	No.	15	33	31	64	57	2.43	1.266	2
		%	7.5	16.5	15.5	32.0	28.5			
3	The department (program) administration implements the medical devices replacement effectively	No.	14	34	30	64	58	2.41	1.261	3
		%	7.0	17.0	15.0	32.0	29.0			
2	The department (program) administration implements national laws and regulations for the medical devices replacement and disposal effectively	No.	13	33	28	70	56	2.39	1.235	4
		%	6.5	16.5	14.0	35.0	28.0			
5	The department (program) administration improves the policy and procedures for the medical devices replacement and disposal periodically	No.	14	30	31	68	57	2.38	1.238	5
		%	7.0	15.0	15.5	34.0	28.5			
Mean								2.43	1.209	

Through the above-stated results, the study individuals disagree on the Planning (Replacement and Disposal(in an average of (2.43 out of 5.00).

Moreover, it is also clear from the results that the study sample individuals disagree on average on nine statements:

1. Statement No. (1) which is “The department (program) administration has a comprehensive written policy and procedures for the medical devices replacement and disposal” in an average of (2.56 out of 5).
2. Statement No. (4) which is “The department (program) administration implements the medical devices disposal effectively” in an average of (2.43 out of 5).
3. Statement No. (3) which is “The department (program) administration implements the medical devices replacement effectively” in an average of (2.41 out of 5).
4. Statement No. (2) which is “The department (program) administration implements national laws and regulations for the medical devices replacement and disposal effectively” in an average of (2.39 out of 5).
5. Statement No. (5) which is “The department (program) administration improves the policy and procedures for the medical devices replacement and disposal periodically” in an average of (2.38 out of 5).

5.3.3 Independent Sample T-test

Table 5.19: Independent Sample T-test “ Hospital type: Governmental/Private”

Item	Hospital type	N	Mean	Std. Deviation	T-test	Sig2
Planning (Assessment of needs, qualifications, resources, support, budget and regulations	Governmental	143	2.40	1.100	-0.820	0.413
	Private	34	2.57	1.044		
Acquisition (evaluation and procurement)	Governmental	143	2.31	1.168	-0.527	0.599
	Private	34	2.43	1.119		
Delivery and Incoming Inspection	Governmental	143	2.32	1.173	-0.921	0.358
	Private	34	2.53	1.182		
Inventory and Documentation	Governmental	143	2.34	1.158	-0.522	0.602
	Private	34	2.46	1.137		
Installation, Commissioning, and Acceptance	Governmental	143	2.30	1.175	-0.601	0.549
	Private	34	2.43	1.150		
Training of Users and Operators	Governmental	143	2.30	1.159	-0.892	0.374
	Private	34	2.50	1.144		
Monitoring of Use and Performance	Governmental	143	2.32	1.143	-1.091	0.277
	Private	34	2.56	1.149		
Maintenance (Corrective, preventive)	Governmental	143	2.34	1.105	-0.721	0.472
	Private	34	2.49	1.020		
Replacement and Disposal	Governmental	143	2.31	1.170	-1.005	0.316
	Private	34	2.53	1.133		

It is clear from the above results; there are no statistically significant differences at the level of 0.05 or less in the directions of the sample members of the study.

Table 5.20: Independent Sample T-test :"Hospital type: Teaching/ Non-Teaching"

Item	Hospital type	N	Mean	Std. Deviation	T-test	Sig. (2-tailed)
Planning (Assessment of needs, qualifications, resources, support, budget and regulations	Teaching	26	2.95	.902	2.654	**0.009
	Non-Teaching	138	2.34	1.102		
Acquisition (evaluation and procurement)	Teaching	26	2.90	.989	2.733	**0.007
	Non-Teaching	138	2.23	1.164		
Delivery and Incoming Inspection	Teaching	26	2.86	1.080	2.340	*0.020
	Non-Teaching	138	2.27	1.191		
Inventory and Documentation	Teaching	26	2.92	1.006	2.705	**0.008
	Non-Teaching	138	2.26	1.165		
Installation, Commissioning, and Acceptance	Teaching	26	2.90	1.000	2.770	**0.006
	Non-Teaching	138	2.21	1.181		
Training of Users and Operators	Teaching	26	2.87	1.003	2.591	**0.010
	Non-Teaching	138	2.24	1.168		
Monitoring of Use and Performance	Teaching	26	2.93	.942	2.760	**0.006
	Non-Teaching	138	2.26	1.154		
Maintenance (Corrective, preventive)	Teaching	26	2.89	.879	2.706	**0.008
	Non-Teaching	138	2.27	1.098		
Replacement and Disposal	Teaching	26	3.01	.981	3.211	**0.002
	Non-Teaching	138	2.22	1.168		

**Function at the level of 0.01 and less *Function at the level of 0.05 and less

It is clear from the above results showed that there are statistically significant differences at the level of 0.05 and less in the directions of the sample of the study according to the type of hospital type for the benefit of university hospitals.

The results had shown that there are statistically significant differences at the level of 0.01 and lower in the attitudes of the study sample members on planning, acquisition, inventory control, documentation, Processing, acceptance, training of users and operators, monitoring use and performance, maintenance (corrective and preventive), replacement and disposal

5.3.4 One Way ANOVA (Hospital type)

Table 5.21: One Way ANOVA (Hospital type)

Item		Sum of Squares	df	Mean Square	F	Sig.
Planning (Assessment of needs, qualifications, resources, support, budget and regulations)	Between Groups	54.070	3	18.023	17.615	**0.000
	Within Groups	190.313	186	1.023		
	Total	244.383	189	-		
Acquisition (evaluation and procurement)	Between Groups	58.500	3	19.500	16.517	**0.000
	Within Groups	219.594	186	1.181		
	Total	278.094	189	-		
Delivery and Incoming Inspection	Between Groups	61.182	3	20.394	16.875	**0.000
	Within Groups	224.794	186	1.209		
	Total	285.977	189	-		
Inventory and Documentation	Between Groups	54.772	3	18.257	15.563	**0.000
	Within Groups	218.196	186	1.173		
	Total	272.968	189	-		
Installation, Commissioning, and Acceptance	Between Groups	54.213	3	18.071	14.764	**0.000
	Within Groups	227.656	186	1.224		
	Total	281.870	189	-		
Training of Users and Operators	Between Groups	52.368	3	17.456	14.429	**0.000
	Within Groups	225.029	186	1.210		
	Total	277.398	189	-		
Monitoring of Use and Performance	Between Groups	50.885	3	16.962	14.529	**0.000
	Within Groups	217.145	186	1.167		
	Total	268.030	189	-		
Maintenance (Corrective, preventive)	Between Groups	48.248	3	16.083	15.328	**0.000
	Within Groups	195.157	186	1.049		
	Total	243.405	189	-		
Replacement and Disposal	Between Groups	52.100	3	17.367	14.221	**0.000
	Within Groups	227.151	186	1.221		
	Total	279.251	189	-		

**Function at the level of 0.01 and less

It is clear from the above results that there are no statistically significant differences at the level of 0.05 or less in the attitudes of the study sample members on planning , acquisition , Documentation, installation, processing and acceptance, training of users and operators, monitoring of use and performance, maintenance (corrective and preventive), replacement and disposal (depending on the type of hospital type). To determine the validity of differences between hospital types, the results are shown as follows:

Table 5.22: differences between public hospitals and medical cities

Item	Hospital type	N	mean	General	Medical city	Specialised	Medical Centre
Planning (Assessment of needs, qualifications, resources, support, budget and regulations	General	107	2.22	-			
	Medical city	35	3.42	**	-		**
	Specialised	27	3.06	**		-	**
	Medical Centre	21	1.88				-
Acquisition (evaluation and procurement)	General	107	2.12	-			
	Medical city	35	3.37	**	-		**
	Specialised	27	2.98	**		-	**
	Medical Centre	21	1.76				-
Delivery and Incoming Inspection	General	107	2.14	-			
	Medical city	35	3.37	**	-		**
	Specialised	27	3.10	**		-	**
	Medical Centre	21	1.76				-
Inventory and Documentation	General	107	2.14	-			
	Medical city	35	3.37	**	-		**
	Specialised	27	2.98	**		-	**
	Medical Centre	21	1.84				-
Installation, Commissioning, and Acceptance	General	107	2.11	-			
	Medical city	35	3.34	**	-		**
	Specialised	27	2.92	*		-	**
	Medical Centre	21	1.82				-
Training of Users and Operators	General	107	2.12	-			
	Medical city	35	3.30	**	-		**
	Specialised	27	2.98	**		-	**
	Medical Centre	21	1.83				-
Monitoring of Use and Performance	General	107	2.15	-			
	Medical city	35	3.37	**	-		**
	Specialised	27	2.93	*		-	*

Item	Hospital type	N	mean	General	Medical city	Specialised	Medical Centre
	Medical Centre	21	1.96				-
Maintenance (Corrective, preventive)	General	107	2.15	-			
	Medical city	35	3.34	**	-		**
	Specialised	27	2.90	**		-	*
	Medical Centre	21	1.96				-
Replacement and Disposal	General	107	2.13	-			
	Medical city	35	3.37	**	-		**
	Specialised	27	2.91	*		-	*
	Medical Centre	21	1.90				-

**Function at the level of 0.01 and less, *Function at the level of 0.05 and less

It is clear from the above results, there are statistically significant differences at the level of 0.01 between public hospitals and medical cities on planning, acquisition, Installation, processing and acceptance, training of users and operators, monitoring use and performance, maintenance (corrective and preventive), replacement and disposal) for the benefit of medical cities.

It is clear from the above results, there are statistically significant differences at 0.01 level between public hospitals and specialised hospitals on planning (needs assessment, resources, support, budget, and regulations required), acquisition, acceptance, training of users and operators, maintenance (corrective and preventive)), in favour of specialised hospitals.

It is clear from the above. The results showed that there are statistically significant differences at the level of 0.01or less between public hospitals and specialised hospitals on (installation, processing, use and performance control, replacement and ventilation) for specialised hospitals.

It is clear from the above results, there are statistically significant differences at the level of 0.01 between health centres and medical cities on planning, acquisition, inventory control and documentation, Installation, processing and acceptance, training of users and operators, monitoring use and performance, maintenance (corrective and preventive), replacement and disposal) for the benefit of medical cities.

It is clear from the above results, there are statistically significant differences at the level of 0.01 between health centres and specialised hospitals on planning, acquisition, delivery, Installation, processing, acceptance, training of users and operators), in favour of specialist hospitals.

It is clear from the above results showed that there are statistically significant differences at the level of 0.05 or less between health centres and specialised hospitals on (use and performance control, maintenance (corrective and preventive), replacement and ventilation) for specialised hospitals.

5.4 Summary of the Chapter

In the chapter is a description of the research outcomes with four sections as the research outcomes; first, the study has collected valuable information about clinical engineering departments from 23 hospitals in Riyadh, Saudi Arabia. Second, designing a questionnaire to evaluate the clinical engineering department services through 64 clinical engineering program indicators. Third, developing the proposed decision support system through 64 clinical engineering program indicators that had been validated by experts in the field to make sure the system is suitable to evaluating current management performance for medical devices maintenance in Saudi Hospitals.

CHAPTER 6: THE PROPOSED DECISION SUPPORT SYSTEM FOR IMPROVING MEDICAL DEVICES MAINTENANCE IN SAUDI ARABIA

6.1 Introduction

The study had reached its primary goal by designing the proposed decision support system including the validation study for the proposed decision support system. The proposed decision support system aims to facilitate the introduction of grades, and the extraction of averages and reporting system is designed using Microsoft Access, the system has four main features: setting, evaluate reports, and resources. The system estimates the evaluation options base on five grades scale as shown in Table 6.1.

Table 6.1: The system evaluation options

Evolution Option	Completely applicable	Somewhat applicable	Middle applicable	Weakly applicable	Not applicable
Grade	5	4	3	2	1

The average result for the evolution display appears as shown in Table 6.2.

Table 6.2: The average result for the evolution display

Grade	4-5	3-3.99	2-2.99	1-1.99
Classification	Excellent	Good	middle	weak

6.2 The Proposed Decision Support System

As a result, for the previous chapter, “Chapter-5: Study Results and Analysis”, that reached the study results and analysis with four sections as the research outcomes; first, the study has collected valuable information about clinical engineering departments from 23 hospitals in Riyadh, Saudi Arabia. Second, designing a questionnaire to evaluate the clinical engineering department services through 64 clinical engineering program indicators. In this section is the achievement by developing the proposed decision support system through 64 clinical engineering program indicators that had been validated by experts in the field to make sure the system is suitable to evaluating current management performance for medical devices maintenance in Saudi hospitals.

The proposed decision support system contains the nine main stages of medical devices maintenance life cycles as follows: 1. Planning 2. Acquisition 3. Delivery and Incoming Inspection 4. Inventory and Documentation 5. Installation, Commissioning, and Acceptance 6. Training of Users and Operators 7. Monitoring of Use and Performance 8. Maintenance 9. Replacement or Disposal

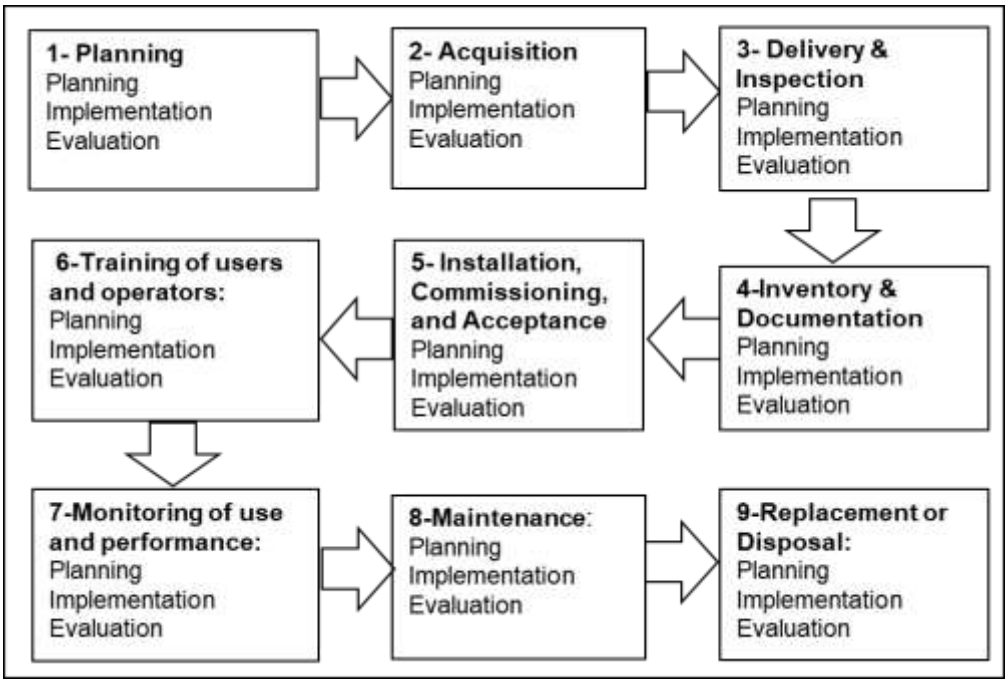


Figure 6.1: The Basic framework for the proposed decision support system

6.3 The Proposed Decision Support System Layout

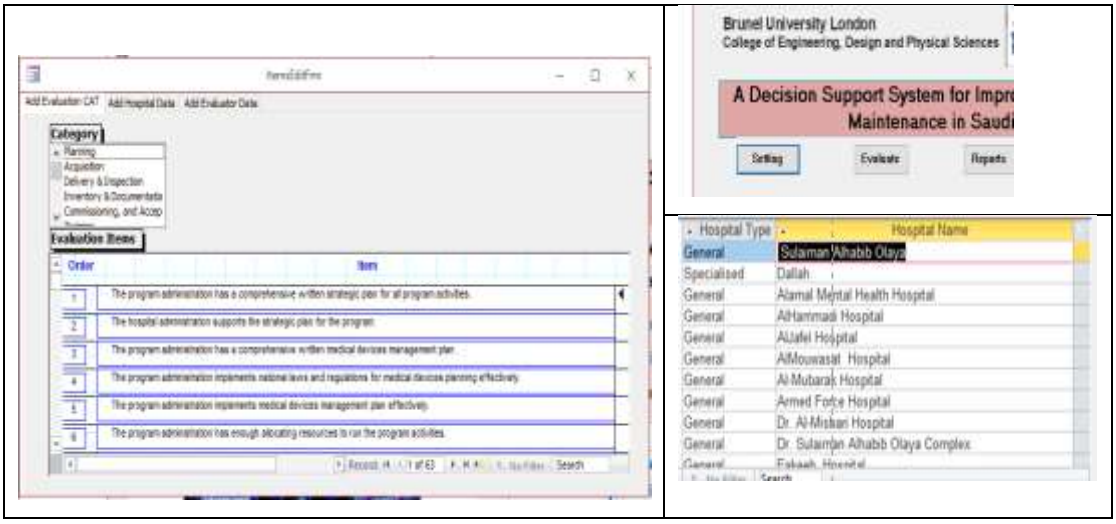
To facilitate the introduction of grades and the extraction of averages and reporting system is designed using Microsoft Access, where the system has four main features: setting, evaluate, reports, and resources

Figure 6.2: The main panel of the system

In the following pages, there is explanation information for each feature.

a) Setting:

the ability to modify items, areas, classifications, to ensure maximum flexibility for the user.



Fugue 6.3: The system setting

b) Evaluate

The ease of entering the answers. When the respondent and the hospital are selected, the terms are displayed in the order in the tool. When recording the score and clicking on the input button, the cursor moves directly to the next statement.

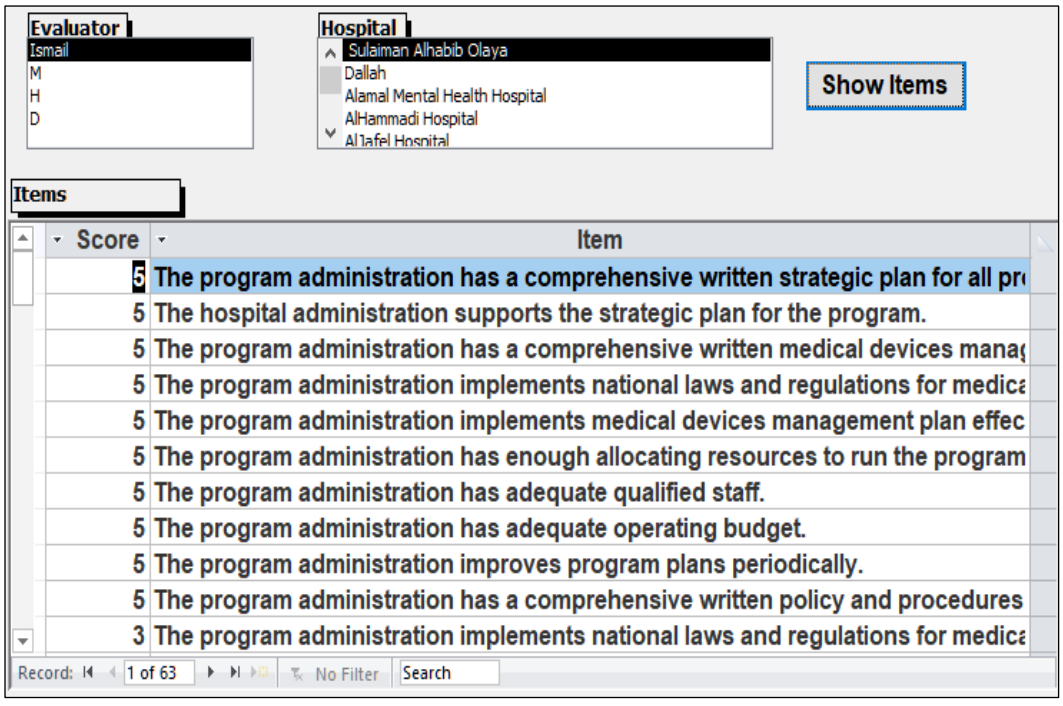


Figure 6.4: the system evaluation panel

c) Reports

The program calculates the averages and extracts the results instantly, whether for the percentage of the terms or the fields, classifications, and elements.

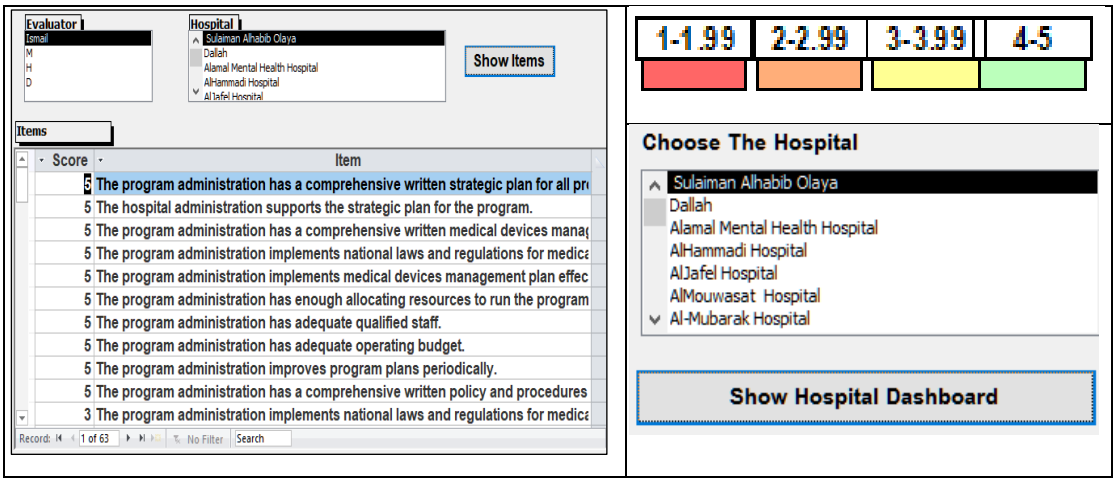


Figure 6.5: the reports panel

The proposed decision support system includes the possibility of displaying an illustration map or dashboard as a basic sketch of the areas showing the colours and numbers of each region according to its evaluation status that shows in figure 6.6.

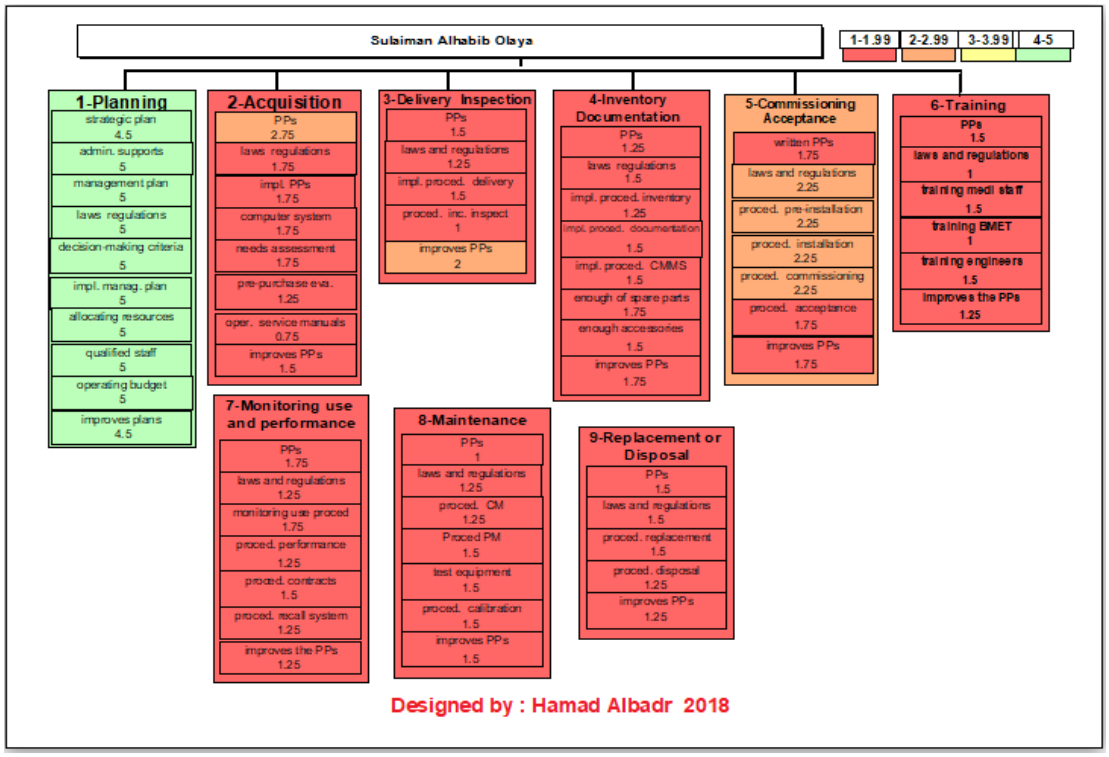


Figure 6.6: The dashboard panel

d) Resources

The proposed decision support system includes ten technical resources to support the decision-making process, as follows:

1. Benchmarking, 2. Definition, 3. End-user Survey, 4. Forms 5. Good practices, 6. KPIs, 7. National Laws and regulations, 8. Policies and Procedures, 9. References and 10. Terminology. The system shows these resources in figure 6.6.

Figure 6.7: the resources panel

Resources-1: Benchmarking

The feature “benchmarking” in the proposed decision support system allows some guidelines and relevant comparisons to similar organisations. The researcher had designed a benchmarking criterion with 40 of experts and peers review for all the 64 KPIs in the system as shown in figure 6.8.

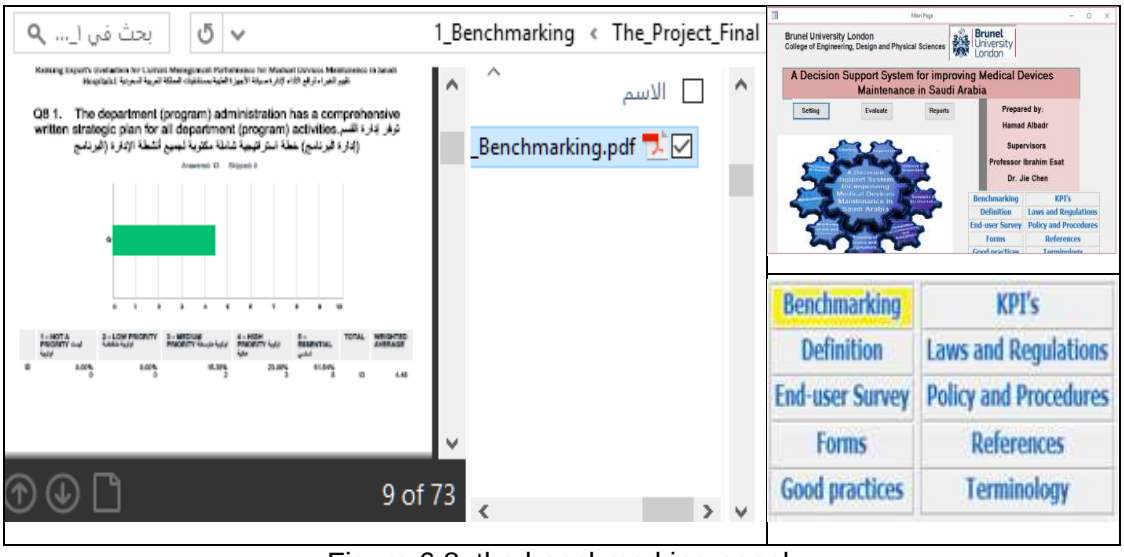


Figure 6.8: the benchmarking panel

Resources-2: Definition

The feature “definition” in the proposed decision support system helps the user to understand the guidelines and relevant definition needed. As shown in Figure 6.9. The researcher had listed a list of definition and terminology from trusted resources.

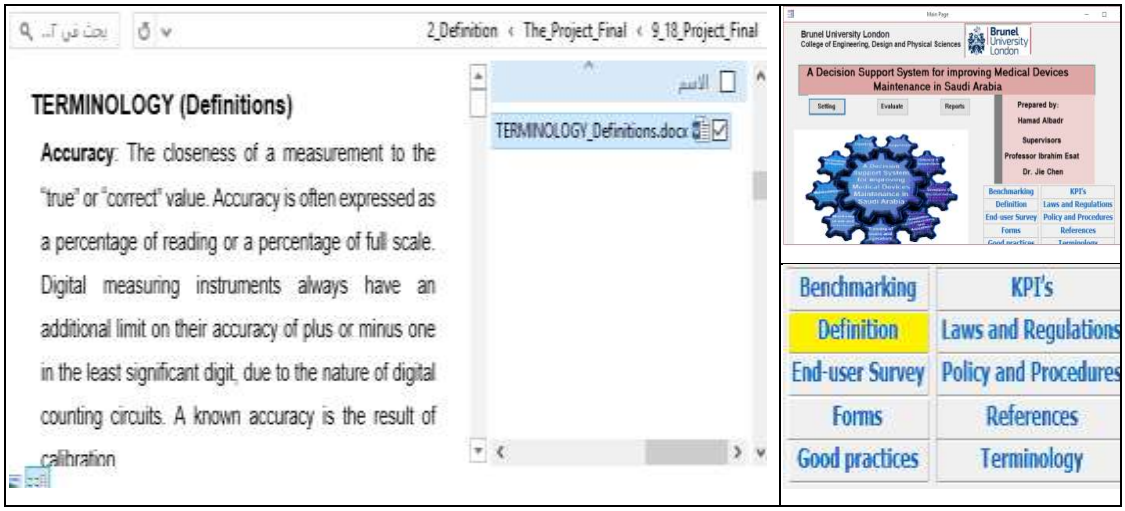


Figure 6.9: the system definition panel

Resources-3: End-user Survey

The feature “end-user survey” in the proposed decision support system helps the user to review “end-user survey results as shown in Figure 6.10. The researcher had listed the full results of the end-user survey.

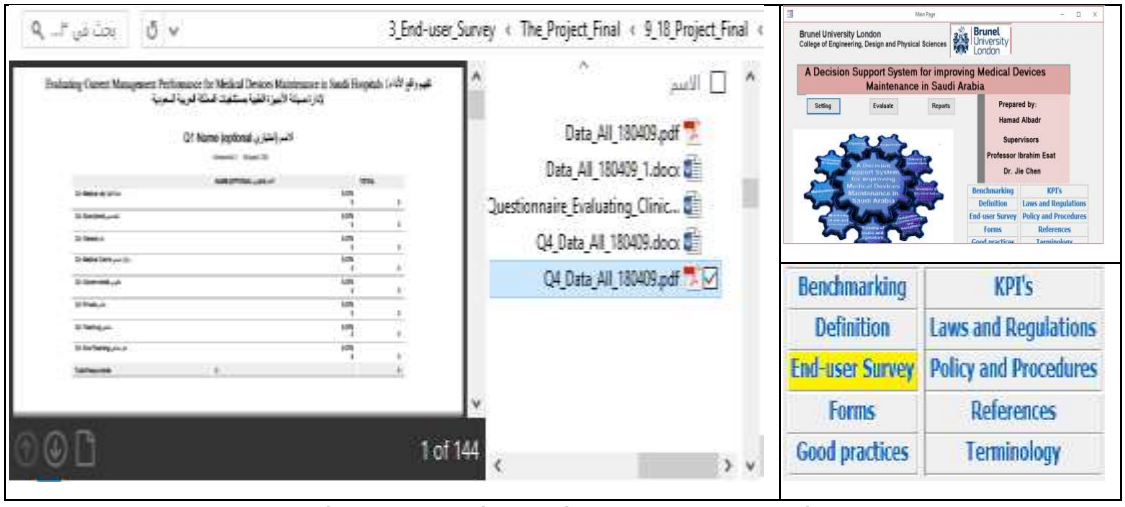


Figure 6.10: the end-user survey panel

Resources-4: Forms

The feature “forms” in the proposed decision support system helps the user to understand the guidelines and relevant Forms needed as shown in Figure 6.11. The researcher had listed a list of forms from trusted resources.

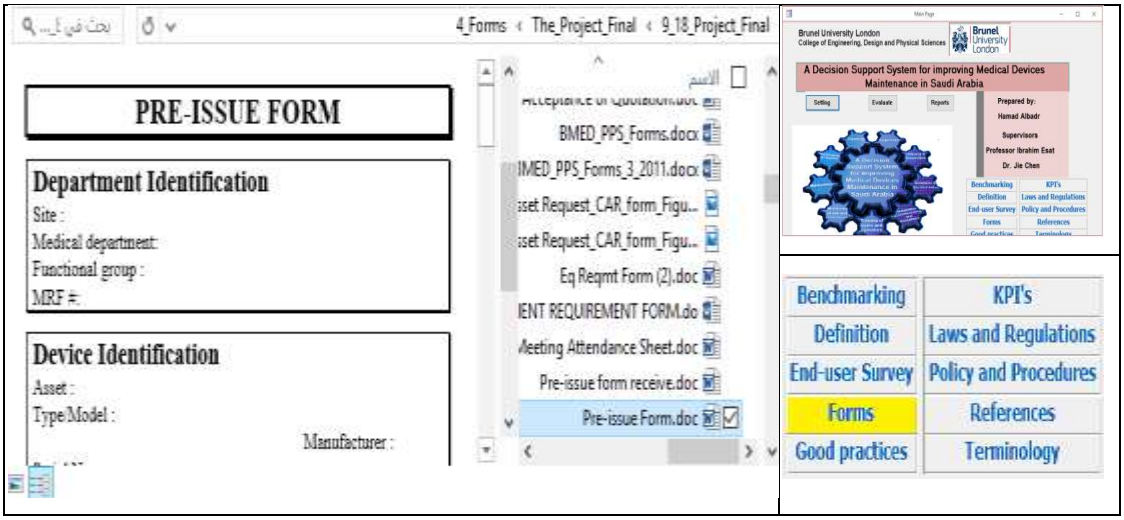


Figure 6.11: the forms panel

Resources-5: Good practices

The feature “good practices” in the proposed decision support system presents the good practices described in this research. The researcher had listed all the good practices described in this research as shown in figure 6.12 from trusted resources.

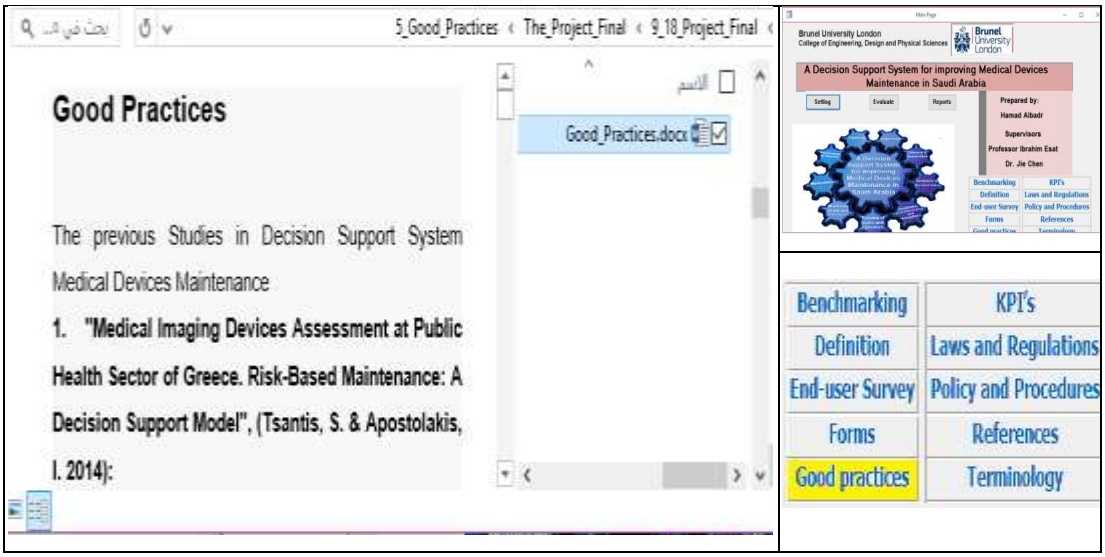


Figure 6.12: the good practices panel

Resources-6: KPIs

The feature “KPIs” in the proposed decision system represents the 64 KPIs in the system to understand the guidelines needed. The researcher had listed all the 64 KPIs in the system as shown in figure 6.8.

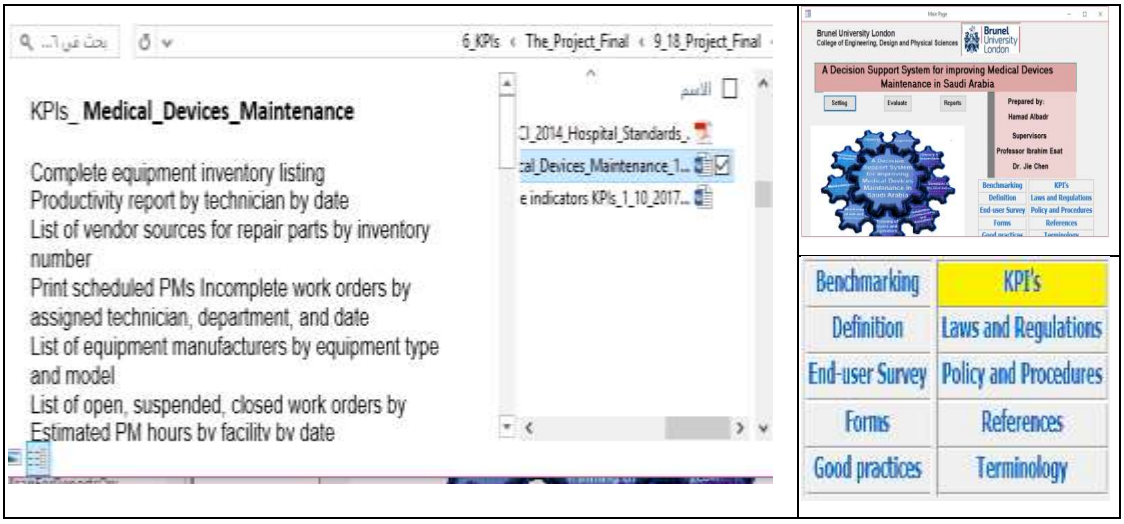


Figure 6.13: the KPIs panel

Resources-7: Laws and regulations

The feature “Laws and regulations” in the proposed decision support system presents a list of national laws and regulations to understand the guidelines and relevant laws needed. The researcher had listed a list of national laws and regulations as shown in Figure 6.14.

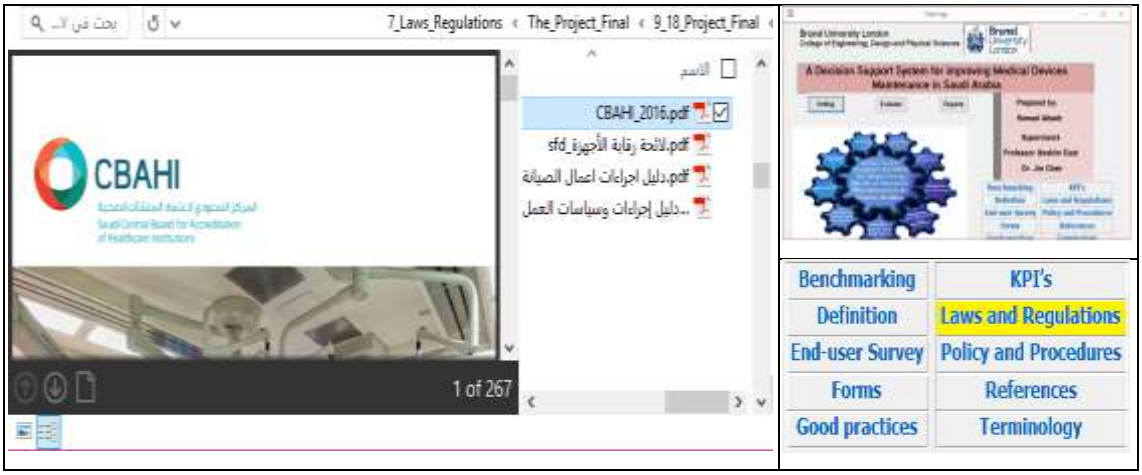


Figure 6.14: the laws and regulations panel

Resources-8: Policies and Procedures

The feature “policies and procedures” in the proposed decision support system presents a list of Policies and Procedures to show these guidelines and relevant laws needed. The researcher had listed a list of policies and procedures as shown in Figure 6.15.

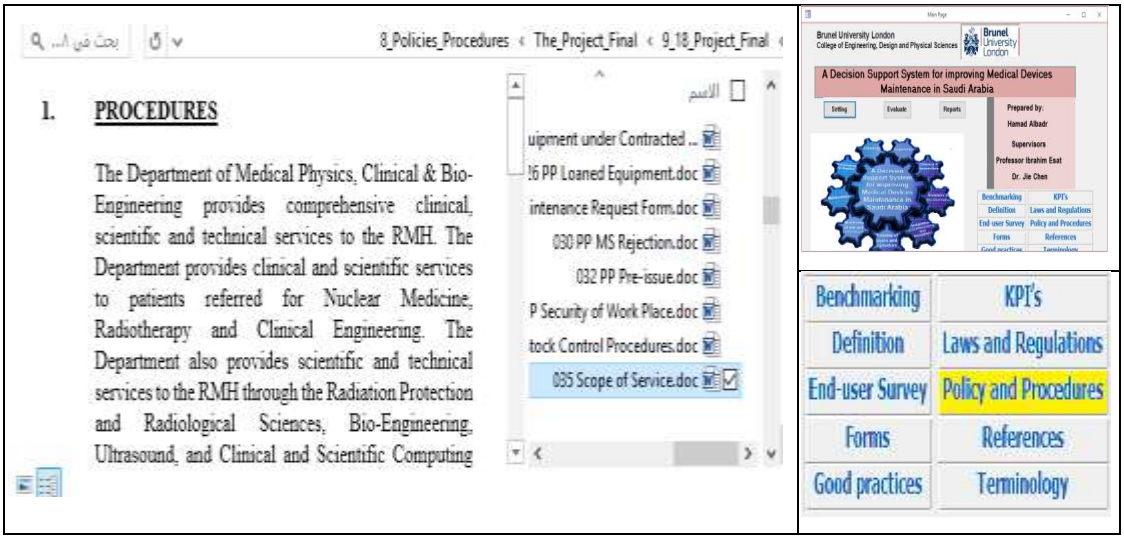


Figure 6.15: the policies and procedures panel

Resources-9: References

The feature “references” in the proposed decision support system presetnts a list of references to having these resources available. The researcher had listed a list of references as shown in Figure 6.16 from trusted resources.

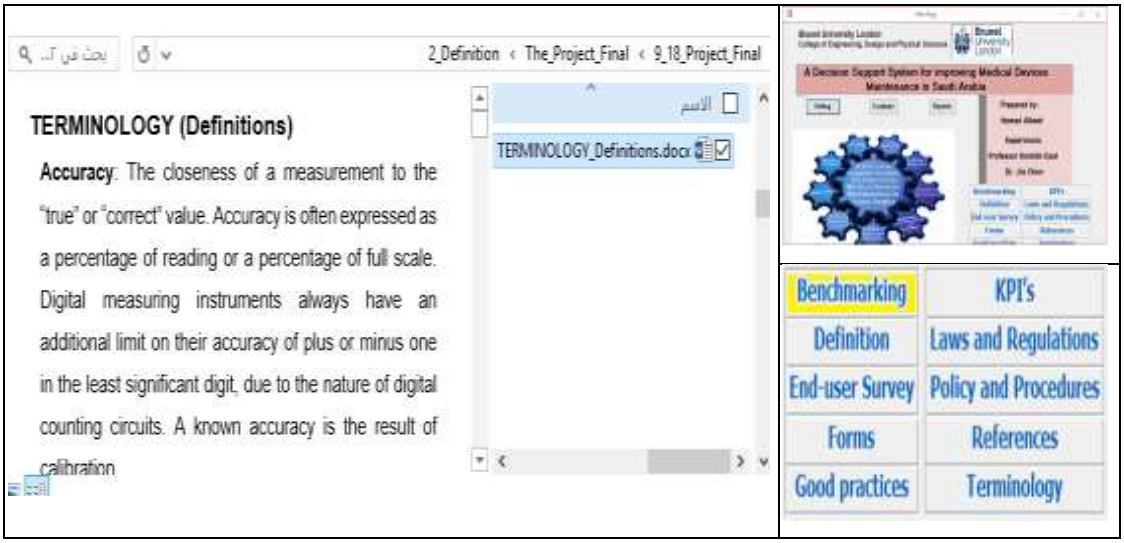


Figure 6.16: the references panel

Resources-10: Terminology

The feature “terminology” in the proposed decision support system presents a list of terminologies to have this information available. The researcher had listed a list of terminologies as shown in Figure 6.17 from trusted resources.

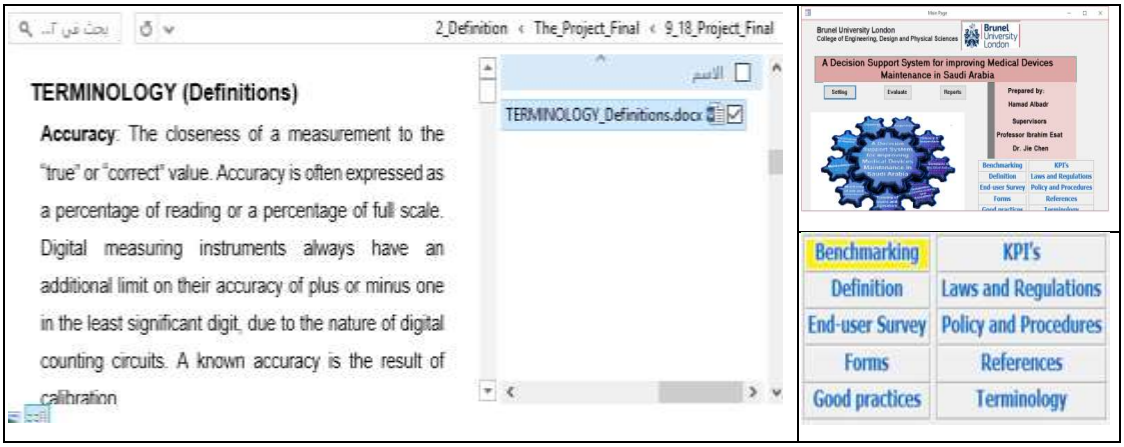


Figure 6.17: the terminology panel

The study had reached its primary goal by designing the proposed decision support system including the validation study for the proposed decision support system. The proposed decision support system aims to facilitate the introduction of grades, and the extraction of averages and reporting software is designed using Microsoft Access, where the system has four main features: setting, evaluate reports, and resources.

6.4 Validation of the Proposed Decision Support System

6.4.1 Introduction

in advance for applying the proposed system for Improving medical devices maintenance in Saudi Hospitals, it is necessary to have a general evaluation of its validation. The life cycle of a system can be divided into the following four phases: Phase I: Concept development, Phase II: Validation, Phase III: Production, Phase IV: Operation. Efficient and effective design can only be achieved by seriously considering maintainability issues that arise during the system life cycle. This means the proposed System must incorporate a dialogue between the decision makers and end-user throughout the system. This dialogue concerns the user’s maintenance needs and other requirements for the system and the decision makers response to these needs and requirements. (Dhillon, 2002).

6.4.2 Validation Result for the Proposed Decision Support System

This section presents the result for the questionnaire of the feedback from experts on applying the proposed decision system for improving medical devices maintenance in Saudi hospitals. The proposed decision support system had achieved a high score on the general evaluation of applying it for Improving medical devices maintenance in Saudi Hospitals with 65.3 % as shown in Table 6.15. Here is the description on the detailed result for the questionnaire in two parts: The distribution of the participants on participants organisation and the result for the questionnaire based on the Technical activities of the life cycles for medical Devices.

Part A: The distribution of the participants on participants organisation

1- Hospital type: General / Specialised/ Medical city, Governmental/Private - Teaching/ Non-Teaching

Table 6.3: The distribution of the participants based on the hospital type

Hospital type	%
Medical city	35 %
Specialised	15 %
General	40 %
Medical Centre	17.5%
Governmental	60 %
Private	22.5%
Teaching	30 %
Non-Teaching	57.5%
TOTAL	100%

2- Position: Director (general manager), Deputy Director, Supervisor, Doctor, Doctor assistant, Nurses, General technician, BMET technicians, Clinical Engineer, Hospital engineer, Administration staff, other

Table 6.4: The distribution of the participants based on the position

Position	%
Director (general manager)	10.00%
Deputy Director	2.50%
Supervisor	15.00%
Doctor	20.00%
Doctor assistant	2.50%
Nurse	5.00%
Administration staff	10.00%
Clinical Engineer	20.00%
Hospital engineer	7.50%
Special Technician	5.00%
BMET technician	2.50%
TOTAL	100%

3- Qualification: PhD. MSc. BSc., Health /Technical College (Diploma), High School

Table 6.5: The distribution of the participants based on the qualification

Qualification	%
PhD.	25.00%
MSc.	30.00%
BSc.	37.50%
Health /Technical College (Diploma) أ	7.50%
TOTAL	100%

4- Average of experience:

Table 6.6: The distribution of the participants based on the average of experience

Average of experience (years)	%
0-5	0.00%
6-10	5.13%
11-15	20.51%
+15	74.36%
TOTAL	100%

Part B: The result for the questionnaire based on the Technical activities

Here is the result for the questionnaire based on the technical activities for medical devices: 1. Planning, 2. Acquisition 3. Delivery and Incoming Inspection; 4. Inventory and Documentation 5. Installation, Commissioning, and Acceptance 6. Training of Users and Operators 7. Monitoring of Use and Performance 8. Maintenance 9. Replacement or Disposal

1- Planning (Assessment of needs, qualifications, resources, support, budget and regulations)

Table 6.7: The result for the feedback on the planning process

Indicator	Ave.(%)
1. The department (program) administration has a comprehensive written strategic plan for all department (program) activities	66
2. The hospital administration supports the strategic plan for the program	65
3. The program administration has a comprehensive written medical devices management plan	64
4. The program administration implements national laws and regulations for medical devices planning effectively	67
5. The program administration implements a comprehensive decision-making criterion for medical devices management plan effectively	68
6. The program administration implements medical devices management plan effectively	65
7. The program administration has enough allocating resources to run the program activities effectively.	63
8. The program administration has adequate qualified staff to run the program activities effectively	60

9. The program administration has an adequate operating budget to run the program activities effectively	70
10. The program administration improves program plans periodically	65
General evaluation on applying the proposed System for Improving technical planning	65.3

2- Acquisition (evaluation and procurement)

Table 6.7: The result for the feedback on the acquisition process

Indicator	Ave. (%)
1. The program administration has a comprehensive written policy and procedures for medical devices acquisition	64
2. The program administration implements national laws and regulations for medical devices acquisition effectively.	65
3. The program administration implements the procedures for medical devices acquisition effectively	63
4. The program administration implements a comprehensive computer system for medical devices acquisition procedures effectively	66
5. The program administration implements the procedures for medical devices needs assessment effectively	62
6. The program administration implements pre-purchase evaluation and selection procedures effectively	67
7. The program administration provides operating and service manuals for medical devices.	67
8. The program administration improves the policy and procedures for medical devices acquisition periodically,	66
General evaluation on applying the proposed System for Improving Acquisition of medical devices	65

3- Delivery and Incoming Inspection

Table 6.8: The result for the feedback on delivery and incoming Inspection process

Indicator	Ave. (%)
1. The program administration has a comprehensive written policy and procedures for medical devices delivery and incoming inspection.	65
2. The program administration implements policy and procedures for medical devices delivery and incoming inspection effectively	62
3. The program administration implements the procedures for medical devices delivery effectively	63
4. The program administration implements the procedures for medical devices incoming inspection effectively.	67
5. The program administration improves policy and procedures for medical devices delivery and incoming inspection periodically.	65
General evaluation on applying the proposed System for Improving delivery and inspection	65

4- Inventory and Documentation

Table 6.9: The result for the feedback on the Inventory and Documentation process

Indicator	Ave. (%)
1. The program administration has a comprehensive written policy and procedures for medical devices inventory and documentation.	64

2. The program administration implements national laws and regulations for medical devices Inventory and documentation effectively.	67
3. The program administration implements the procedures for medical devices inventory effectively.	65
4. The program administration implements the procedures for medical devices documentation effectively	67
5. The program administration implements a comprehensive computerised maintenance management system (CMMS) effectively	62
6. The program administration provides enough inventory of spare parts for medical devices	64
7. The program administration provides enough inventory of accessories for medical devices	68
8. The program administration improves the policy and procedures for medical devices inventory and documentation periodically.	67
General evaluation on applying the proposed System for Improving inventory and documentation	65.5

5- Installation, Commissioning, and Acceptance

Table 6.10: The result for the feedback on Installation, Commissioning, and Acceptance process

Indicator	Ave. (%)
1. The program administration has a comprehensive written policy and procedures for medical devices installation, commissioning, and acceptance.	64
2. The program administration implements national laws and regulations for medical devices installation, commissioning, and acceptance effectively.	65
3. The program administration implements the procedures for medical devices pre-installation requirements effectively.	66
4. The program administration implements the procedures for medical devices installation effectively.	67
5. The program administration implements the procedures for medical devices commissioning effectively.	63
6. The program administration implements the procedures for medical devices acceptance effectively.	68
7. The program administration improves the policy and procedures for medical devices installation, commissioning, and acceptance periodically.	64
General evaluation on applying the proposed System for Improving installation, commissioning, and acceptance	65.3

6- Training of Users and Operators

Table 6.11: The result for the feedback on the Training of Users and Operators process

Indicator	Ave. (%)
1. The program administration has a comprehensive written policy and procedures for medical devices training of users and operators.	64

2. The program administration implements national laws and regulations for medical devices training of users and operators effectively.	67
3. The program administration implements the medical devices training procedures for medical staff effectively.	66
4. The program administration implements the medical devices training procedures for BMET effectively.	67
5. The program administration implements the medical devices training procedures for clinical engineers effectively.	63
6. The program administration improves the policy and procedures for medical devices training of users and operators periodically.	66
General evaluation on applying the proposed System for Improving training of users and operators	65.5

7- Monitoring of Use and Performance

Table 6.12: The result for the feedback on Monitoring of Use and Performance process

Indicator	Ave. (%)
1. The program administration has a comprehensive written policy and procedures for the medical devices monitoring of use and performance.	66
2. The program administration implements national laws and regulations for the medical devices monitoring of use and performance effectively.	68
3. The program administration implements the procedures for the medical devices monitoring of use effectively.	64
4. The department (program) administration implements the procedures for monitoring medical devices safety effectively.	65
5. The department (program) administration implements the policy and procedures for the medical devices performance effectively	67
6. The department (program) administration implements the procedures for the medical devices contracts management effectively.	66
7. The department (program) administration implements the procedures for recall system for the medical devices with the National Centre for Medical Devices Reporting effectively	63
8. The department (program) administration improves the policy and procedures for the medical devices monitoring of use and performance periodically.	64
General evaluation on applying the proposed System for Improving monitoring of use and performance	65.3

8- Maintenance (Corrective, preventive)

Table 6.13: The result for the feedback on Maintenance process

Indicator	Ave. (%)
1. The program administration has a comprehensive written policy and procedures for medical devices maintenance.	64
2. The department (program) administration applies national laws and regulations for medical devices maintenance effectively.	67

3. The department (program) administration implements the procedures for the corrective maintenance for medical devices effectively	63
4. The department (program) administration implements the procedures of the preventive maintenance for the medical devices effectively	68
5. The department (program) administration provides adequate space for the workshop for medical devices maintenance	67
6. The department (program) administration provides operating and service manuals for medical devices	63
7. The department (program) administration provides adequate spare parts for medical devices	65
8. The department (program) administration provides appropriate tools and equipment for medical devices maintenance	66
9. The department (program) administration provides adequate appropriate test and measurement equipment for medical devices maintenance.	64
10. The department (program) administration calibrates the test and measurement equipment periodically.	68
11. The department (program) administration improves the policy and procedures for the medical devices maintenance periodically.	67
General evaluation on applying the proposed System for Improving maintenance	65.6

9- Replacement and Disposal

Table 6.14: The result for the feedback on the replacement and disposal process

Indicator	Ave (%)
1. The program administration has a comprehensive written policy and procedures for medical devices replacement and disposal.	64
2. The program administration implements national laws and regulations for the medical device's replacement and disposal effectively	66
3. The program administration implements the medical devices replacement effectively	65
4. The program administration implements the medical devices disposal effectively.	68
5. The program administration improves the policy and procedures for the medical devices replacement and disposal periodically.	63
General evaluation on applying the proposed System for Improving replacement and disposal.	65.2

The General evaluation:

The General evaluation of applying the proposed System for Improving Medical Devices Maintenance in Saudi Hospitals is 65.3 % as shown in Table 6.15.

Table 6.15: The result for the feedback on the general evaluation of applying the proposed System

General evaluation	Ave. (%)
General evaluation of applying the proposed System for Improving Medical Devices Maintenance in Saudi Hospitals	65.3

6.5 Summary of the Chapter

As a summary of the chapter, in this chapter, a description of the proposed decision support system with four sections, that includes the validation study for the proposed decision support system. The proposed decision support system had achieved a high score on the general evaluation of applying it for Improving medical devices maintenance in Saudi Hospitals with 65.3 % as shown in Table 6.15.

CHAPTER 7: STUDY CONCLUSION AND RECOMMENDATIONS

7.1 Introduction

In this chapter, a description of the conclusion and recommendations of the study with four sections; the study conclusion, the study recommendations, the research limitations and the future work.

7.2 The study Conclusion:

In this section, a presentation for the study conclusion related to study individual's description and the study results related to the technical activities.

7.2.1 The Study Conclusion Related to the Individual's Description

The total number of (107) of the study individuals representing 53.5% of total study individuals the Hospital type is General, whereas (35) of them representing 17.5% of total study individuals the Hospital type is Medical city, against (27) of them representing 13.5% of total study individuals the Hospital type is Specialised, whereas (21) of them representing 10.5% of total study individuals the Hospital type is Medical Centre .

The total number of (143) of the study individuals representing 71.5% of total study individuals the Hospital type is Governmental**,** whereas (34) of them representing 17.0% of total study individuals the Hospital type is Private.

The total number of (138) of the study individuals representing 69.0% of total study individuals the Hospital type is Non-Teaching, whereas (26) of them representing 13.0% of total study individuals the Hospital type is Teaching.

The total number of (30) of the study individuals represents 15.0% of total study individuals in the Position is BMET technician, whereas (29) of them representing 14.5% of total study individuals the Position is Clinical Engineer, against (25) of them representing 12.5% of total study individuals the Position is Administration staff, whereas (22) of them representing 11.0% of total study individuals the Position is

Special Technician , whereas (20) of them representing 10.0% of total study individuals the Position is Nurse , whereas (15) of them representing 7.5% of total study individuals the Position is Doctor , whereas (15) of them representing 7.5% of total study individuals the Position is Doctor assistant , whereas (13) of them representing 6.5% of total study individuals the Position is Hospital engineer , whereas (12) of them representing 6.0% of total study individuals the Position is Supervisor, whereas (10) of them representing 5.0% of total study individuals the Position is Director (general manager), whereas (9) of them representing 4.5% of total study individuals the Position is Deputy Director .

The total number of (71) of the study individuals represents 35.5% of total study individuals the Qualification is BSc , whereas (52) of them representing 26.0% of total study individuals the Qualification is Health /Technical College (Diploma), against (49) of them representing 24.5% of total study individuals the Qualification is MSc, whereas (19) of them representing 9.5% of total study individuals the Qualification is High School, whereas (9) of them representing 4.5% of total study individuals the Qualification is PhD.

The total number of (69) of the study individuals who represents 34.5% of total study individuals the Average of experience is 6-10 years, whereas (65) of them representing 32.5% of total study individuals the Average of expertise is 11-15 years, against (37) of them representing 18.5% of total study individuals the Average of experience is 15 years and more, whereas (29) of them representing 14.5% of total study individuals the Average of experience is 0-5 years.

7.2.2 The Study Conclusion Related to the Technical Activities

1- Planning

The study individuals disagree with the Planning (Assessment of requirements, necessities, resources, support, budget, and regulations).

It is clear from the results; the study sample individuals are Undecided (Neutral) on the statements which are “The department (program) administration has a comprehensive written strategic plan for all department (program) activities.

Moreover, it is also clear from the results that the study sample individuals disagree on average on nine statements:

1. The department (program) administration has enough allocating resources to run the department (program) activities effectively.
2. The department (program) administration implements a comprehensive decision-making criterion for medical devices management plan effectively.
3. The department (program) administration has a comprehensive written medical devices management plan.
4. The department (program) administration implements medical devices management plan effectively.
5. The department (program) administration implements national laws and regulations for medical devices planning effectively.
6. The hospital administration supports the strategic plan for the department (program).
7. The department (program) administration has adequate qualified staff to run the department (program) activities effectively.
8. The department (program) administration improves department (program) plans periodically.
9. The department (program) administration has an adequate operating budget to run the department (program) activities effectively.

2- Acquisition (evaluation and procurement)

The study individuals disagree on the Acquisition (evaluation and procurement)

Moreover, it is also clear from the results that the study sample individuals disagree on average on six statements:

1. The department (program) administration has a comprehensive written policy and procedures for medical devices acquisition.
2. The department (program) administration implements pre-purchase evaluation and selection procedures effectively.
3. The department (program) administration implements national laws and regulations for medical devices acquisition effectively.

4. The department (program) administration implements a comprehensive computer system for medical devices acquisition procedures effectively.
5. The department (program) administration improves the policy and procedures for medical devices acquisition periodically.
6. The department (program) administration implements the procedures for medical devices acquisition effectively.

3- Delivery and Incoming Inspection

The study individuals disagree with the Delivery and Incoming Inspection

Moreover, it is also clear from the results that the study sample individuals disagree on average on five statements:

1. The department (program) administration has a comprehensive written policy and procedures for medical device delivery and incoming inspection.
2. The department (program) administration implements the procedures for medical devices incoming inspection effectively.
3. The department (program) administration implements national laws and regulations for medical devices planning effectively.
4. The department (program) administration implements the procedures for medical device delivery effectively.
5. The department (program) administration improves policy and procedures for medical device delivery and incoming inspection periodically.

4- Inventory and Documentation

Through the above-stated results, the study individuals disagree with the Inventory and Documentation.

Moreover, it is also clear from the results that the study sample individuals disagree on average on eight statements:

1. The department (program) administration implements the procedures for medical device documentation effectively.
2. The department (program) administration has a comprehensive written policy and procedures for medical devices inventory and documentation.

3. The department (program) administration implements a comprehensive computerised maintenance management system (CMMS) effectively.
4. The department (program) administration implements national laws and regulations for medical device inventory and documentation effectively.
5. The department (program) administration provides enough inventory of spare parts for medical devices.
6. The department (program) administration implements the procedures for medical devices inventory effectively.
7. The department (program) administration provides enough inventory of accessories for medical devices.
8. The department (program) administration improves the policy and procedures for medical devices inventory and documentation periodically.

5- Installation, Commissioning, and Acceptance

The study individuals disagree with the Installation, Commissioning, and Acceptance.

Moreover, it is also clear from the results that the study sample individuals disagree on average on six statements:

1. The department (program) administration has a comprehensive written policy and procedures for medical device installation, commissioning, and acceptance.
2. The department (program) administration implements national laws and regulations for medical device installation, commissioning, and acceptance effectively.
3. The department (program) administration implements the procedures for medical devices-installation requirements effectively.
4. The department (program) administration implements the procedures for medical devices acceptance effectively.
5. The department (program) administration implements the procedures for medical device installation effectively.
6. The department (program) administration improves the policy and procedures for medical device installation, commissioning, and acceptance periodically.

6- Training of Users and Operators

The study individuals disagree with the Training of Users and Operators

Moreover, it is also clear from the results that the study sample individuals disagree on average on six statements:

1. The department (program) administration has a comprehensive written policy and procedures for medical devices training of users and operators.
2. The department (program) administration implements the medical devices training procedures for clinical engineers effectively.
3. The department (program) administration implements national laws and regulations for medical devices training of users and operators effectively.
4. The department (program) administration implements the medical devices training procedures for BMET effectively.
5. The department (program) administration improves the policy and procedures for medical devices training of users and operators periodically.
6. The department (program) administration implements the medical devices training procedures for medical staff effectively.

7- Monitoring of Use and Performance

The study individuals disagree on the Monitoring of Use and Performance.

Moreover, it is also clear from the results that the study sample individuals disagree on average on eight statements:

1. The department (program) administration has a comprehensive written policy and procedures for the medical devices monitoring of use and performance.
2. The department (program) administration implements the procedures for monitoring medical devices safety effectively.
3. The department (program) administration implements the procedures for a recall system for the medical devices with the National Centre for Medical Devices Reporting effectively.
4. The department (program) administration implements the policy and procedures for the medical devices performance effectively.
5. The department (program) administration implements the procedures for the medical devices monitoring of use effectively.
6. The department (program) administration implements national laws and regulations for the medical devices monitoring of use and performance effectively.

7. The department (program) administration implements the procedures for the medical device's contracts management effectively.
8. The department (program) administration improves the policy and procedures for the medical devices monitoring of use and performance periodically.

8- Maintenance (Corrective, preventive)

The study individuals disagree on the Maintenance (Corrective, preventive).

Moreover, it is also clear from the results that the study sample individuals disagree on average on 11 statements:

1. The department (program) administration has a comprehensive written policy and procedures for medical devices maintenance.
2. The department (program) administration provides adequate space for the workshop for medical device maintenance.
3. The department (program) administration implements the procedures of the preventive maintenance for the medical devices effectively.
4. The department (program) administration provides appropriate tools and equipment for medical devices maintenance.
5. The department (program) administration provides adequate, appropriate test and measurement equipment for medical devices maintenance.
6. The department (program) administration provides adequate spare parts for medical devices.
7. The department (program) administration provides operating and service manuals for medical devices.
8. The department (program) administration implements the procedures of the corrective maintenance for the medical devices effectively.
9. The department (program) administration calibrates the test and measurement equipment periodically.
10. The department (program) administration implements national laws and regulations for the medical device's maintenance effectively.
11. The department (program) administration improves the policy and procedures for the medical devices maintenance periodically.

9- Replacement and Disposal

The study individuals disagree on the Replacement and Disposal.

Moreover, it is also clear from the results that the study sample individuals disagree on average on five statements:

1. The department (program) administration has a comprehensive written policy and procedures for the medical devices replacement and disposal.
2. The department (program) administration implements the medical devices disposal effectively.
3. The department (program) administration implements the medical devices replacement effectively.
4. The department (program) administration implements national laws and regulations for the medical device's replacement and disposal effectively.
5. The department (program) administration improves the policy and procedures for the medical devices replacement and disposal periodically.

The results show that there are no statistically significant differences at the level of 0.05 or less in the directions of the sample members of the study.

The results showed that there are statistically significant differences at the level of 0.01 and lower in the attitudes of the study sample members on planning, acquisition, inventory control, documentation, Processing, acceptance, training of users and operators, monitoring use and performance, maintenance (corrective and preventive), replacement and disposal.

The results showed that there are statistically significant differences at the level of 0.01 between public hospitals and medical cities on planning, acquisition, Installation, processing and acceptance, training of users and operators, monitoring use and performance, maintenance (corrective and preventive), replacement and disposal) for the benefit of medical cities.

The results showed that there are statistically significant differences at the level of0.01 or less between public hospitals and specialised hospitals on planning, acquisition, Acceptance, training of users and operators, maintenance (corrective and preventive)), in favour of specialised hospitals.

The results showed that there are statistically significant differences at the level of 0.01 or less between public hospitals and specialised hospitals on installation, processing, use and performance control, replacement and disposal for specialised hospitals.

The results showed that there are statistically significant differences at the level of 0.01 between health centres and medical cities on planning, acquisition, inventory control and documentation, Installation, processing and acceptance, training of users and operators, monitoring use and performance, maintenance (corrective and preventive), replacement and disposal) for the benefit of medical cities.

The results showed that there are statistically significant differences at the level of 0.01 between health centres and specialised hospitals on planning, acquisition, delivery, Installation, processing, acceptance, training of users and operators), in favour of specialist hospitals.

The results showed that there are statistically significant differences at the level of 0.05 or less between health centres and specialised hospitals on (use and performance control, maintenance (corrective and preventive), replacement and ventilation) for specialised hospitals.

7.3 Study Recommendations

1. Advice the ministry of health in Saudi Arabia and the health care organisation to support the proposed system.
2. Advice the biomedical engineering departments directors in Saudi Arabia to provide enough resources to run the activities of the department effectively.
3. Urge the biomedical engineering departments directors in the Kingdom of Saudi Arabia to implement a comprehensive plan for the decision-making mechanism to manage the maintenance of medical devices effectively.
4. Advice the biomedical engineering departments directors in Saudi Arabia to implement a comprehensive written plan to manage the maintenance of medical devices.
5. Advice the biomedical engineering departments directors to direct the department management to implement the plan to maintain medical devices effectively.
6. Encourage department management to apply national regulations and legislation to plan the maintenance of medical devices effectively.
7. Advice the biomedical engineering departments directors to improve the quality of the performance of the ownership (acquisition) of medical devices.

8. Advice the biomedical engineering departments directors to improve to addres the shortcomings in the performance of delivery performance and examination of receipt of medical devices in the departments.
9. Working to improve the performance of inventory control and documentation of medical devices in the departments.
10. Advice the biomedical engineering departments directors to improve to improve the quality of performance in the performance of installation, processing, and acceptance of medical devices in the departments.
11. Advice the biomedical engineering departments directors to improve to improve the training of users and operators in the departments.
12. Advice the biomedical engineering departments directors to improve the performance of the reality of monitoring the use and performance of the departments .
13. Advice the biomedical engineering departments directors to improve the quality of the performance of the reality of maintenance (corrective and preventive) in the departments.
14. Advice the biomedical engineering departments directors to improve the performance of the reality of replacement and disposal in the departments.

7.4 The Study Limitations

The research has some limitations. They are:

a. The place limitation: Hospitals at Saudi Arabia capital city, Riyadh.
b. The period limit: 2015-2017.
c. The subject limit: Identifying the parameters involved in medical devices maintenance in Saudi Arabia, the best international practice experiences in medical devices maintenance, and Designing a Decision Support System for improving medical devices maintenance in Saudi Arabia.

7.5 The Future Work

1. Improving the new decision support system by applying it in some hospitals to monitor medical devices maintenance in Saudi Arabia.
2. Improving the new decision support system to work with larger data such as Oracle.

3. Making the new decision support system available online and in the smartphone's applications.
4. Developing an Interactive tool with the existing medical devices maintenance management system.

As a summary for this chapter, it has been discussed, a description of the conclusion and recommendations of the study with four sections; the study results, the study recommendations, the research limitations and the future work.

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Appendix-1: Survey of Clinical Engineering Departments in Saudi Arabia

Survey of Clinical engineering Departments in Saudi Arabia: Structure, Personnel, Responsibilities, Resources

Please, complete this survey and return it to Hamad Albadr, PhD candidate at Brunel University London, P. O. Box. 88192 Riyadh 11662. Tel. +966-11-4704090, Cell phone +966-555-450585, E-mail: hamad.albadr@brunel.ac.uk or hamadbadr@gmail.com .

Section-1: Contact information

Your Name: _____ Position: _____ E-mail address: _____

Telephone: _____ Fax: _____

Hospital name: _____

Postal address: P. O. Box _____ Post code _____

Section-2: Hospital information

Hospital type (please chick): Teaching ( ) General ( ) Non-Teaching ( ) Specialised hospital ( ) Other, please specify _____

Number of Hospital Beds _____ Number of ICU (intensive-care unit) Beds _____

Section-3: Clinical Engineering Department Profile:

Approximate value of the medical devices in the hospital (in Saudi Riyals) ____

Approximate budget for new medical devices per year (in Saudi Riyals) _____

Number of devices supported by the CLINICAL ENGINEERING DEPARTMENT_____ Approx. value of the medical devices under the clinical engineering department (in Saudi Riyals) _____

Section-4: Structure:

The Biomedical Engineering services function as (please tick ☑): ( ) a separate department, established in _____ (year). Or ( ) part of another department/unit (please specify) _____

Whom does the department/ unit report to? _____

Are you satisfied with the reporting authority? ( ) Yes ( ) No

How much is the allocated space? _____ m^2.

Section-5: Personnel: Number of employees, qualifications (the highest degree), average age and years of professional experience (specify the numbers in each box)

Personnel	University		Technical College (after the high school)				High School	Average	Average Years of the profession
	PhD.	M.Sc.	B.Sc.	3 years	2 years	1 year	3 years	Age	
Engineers									
BMETs									
Clerk staff									
Others									

Number of clerical staff _____

How many biomedical engineers are certified _____ Technicians _____?

How many are members of national and/or international professional associations?

Biomedical engineers _____ Technicians _____

How often does the clinical engineering department personnel take training courses (please tick)? ( ) Every 6 mons., ( ) Every 12 mons., ( ) Every 24 mons., ( )Not at all.

Section-6: Responsibilities

No	What is the distribution of the time of the Department in general, engineers, and technicians	Department in general (%)
1	Administration	
2	Equipment Inventory	
3	Preventive Maintenance (PM)	
4	Corrective Maintenance (CM)	
5	Pre-purchase Consultation:	
6	Acceptance Testing (Incoming Inspections)	
7	Management of Service Contracts	
8	Risk Management	
9	Quality Control	
10	Education and Training	
11	Research and Development	

Section-7: Resources:

1. Is the number of personnel adequate? ( )Y, ( )N. If “No”, please state additional personnel required: Engineers _____Technicians _____
2. Is the provided occupancy area adequate? ( )Y, ( )N.
3. Is the available test equipment adequate for performing your duties? ( )Y, ( )N
4. Is the parts inventory adequate? ( )Y, ( )N .
5. Is the available technical (service) documentation adequate? ( )Y, ( )N
6. Do you have a computerised system for management of the inventory and the maintenance of the equipment? ( )Y, ( )N
7. Do you have a quality assurance program? ( )Y, ( )N
8. Do you use a productivity index to measure staff performance? ( )Y, ( )N
9. Do you feel that the clinical engineering department in your hospital is well accepted and its work recognised? ( )Y, ( )N

APPENDIX-2: Questionnaire of Evaluating Current Management Performance for Medical Devices Maintenance in Saudi Hospitals

Dear colleague,

Heartfelt greetings

It is my pleasure to invite you to participate in this survey to evaluate the quality of medical devices maintenance services and technical activities that carried out by the program administration or clinical engineering department in Saudi Arabian hospitals, as a part of completing a PhD thesis in biomedical engineering at Brunel University London.

The questionnaire addresses the evaluation of nine technical activities, namely:

1- Technical planning (needs assessment, resources, support, budget and regulations)
2- Acquisition of medical devices (acquisition, evaluation and purchase)
3- Delivery and Inspection
4- Inventory and Documentation
5- Installation, commissioning, and acceptance
6- Training of users and operators
7- Monitoring of use and performance
8- Maintenance (Corrective, Preventive)
9- Replacement and Disposal

I hope that you will fill out this questionnaire to assess the performance of the program management in your health facility from your point of view by determining the extent to which each statement applies to five levels: Strongly Agree ( ) Agree ( ) Undecided(Neutral) ( ) Disagree ( ) Strongly Disagree ( ), by this link:

https://www.surveymonkey.com/r/SHQL5YX

Finally, I would like to express my thanks to you in advance for your cooperation in answering. The data collected will be for scientific research purposes only.

For further information, you can contact me at 0555450585 or hamadbadr@gmail.com.

Thank you very much for your cooperation and support.

Best Regards,

Hamad Albadr

Section A: General Information

1. Name (optional): ..... email: (optional): .....

Hospital type (please, check one): General / Specialised/ Medical city, Governmental/Private -Teaching/ Non-Teaching.

2. **Position**: Director (general manager), Deputy Director, Supervisor, Doctor, Doctor assistant, Nurses, General technician, BMET technicians, Clinical Engineer, Hospital engineer, Administration staff, other

3. **Qualification**: PhD, MSc, BSc., Health /Technical College (Diploma), High School

4. **Average of experience** (check one): 0-5. 6-10, 11-15, +15

Section B: Technical activities for medical Devices

1. **Planning**

1. The program administration has a comprehensive written strategic plan for all program activities.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

2. The hospital administration supports the strategic plan for the program.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

3. The program administration has a comprehensive written medical devices management plan.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

4. The program administration implements national laws and regulations for medical devices planning effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

5. The program administration implements a comprehensive decision-making criterion for medical devices management plan effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

6. The program administration implements medical devices management plan effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

7. The program administration has enough allocating resources to run the program activities effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

8. The program administration has adequate qualified staff to run the program activities effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

9. The program administration has adequate operating budget to run the program activities effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

10. The program administration improves program plans periodically.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

2. Acquisition (evaluation and procurement)

1. The program administration has a comprehensive written policy and procedures for medical devices acquisition

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

2. The program administration implements national laws and regulations for medical devices acquisition effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

3. The program administration implements the procedures for medical devices acquisition effectively

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

4. The program administration implements a comprehensive computer system for medical devices acquisition procedures effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

5. The program administration implements the procedures for medical devices needs assessment effectively

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

6. The program administration implements pre-purchase evaluation and selection procedures effectively

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

7. The program administration provides operating and service manuals for medical devices.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

8. The program administration improves the policy and procedures for medical devices acquisition periodically.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

3. Delivery and Incoming Inspection

1. The program administration has a comprehensive written policy and procedures for medical devices delivery and incoming inspection.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

2. The program administration implements policy and procedures for medical devices delivery and incoming inspection effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

3. The program administration implements the procedures for medical devices delivery effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

4. The program administration implements the procedures for medical devices incoming inspection effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

5. The program administration improves policy and procedures for medical devices delivery and incoming inspection periodically.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

4. Inventory and Documentation

1. The program administration has a comprehensive written policy and procedures for medical devices inventory and documentation.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

2. The program administration implements national laws and regulations for medical devices Inventory and documentation effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

3. The program administration implements the procedures for medical devices inventory effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

4. The program administration implements the procedures for medical devices documentation effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

5. The program administration implements a comprehensive computerised maintenance management system (CMMS) effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

6. The program administration provides enough inventory of spare parts for medical devices.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

7. The program administration provides enough inventory of accessories for medical devices.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

8. The program administration improves the policy and procedures for medical devices inventory and documentation periodically.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

5. Installation, Commissioning, and Acceptance

1. The program administration has a comprehensive written policy and procedures for medical devices installation, commissioning, and acceptance.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

2. The program administration implements national laws and regulations for medical devices installation, commissioning, and acceptance effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

3. The program administration implements the procedures for medical devices pre-installation requirements effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

4. The program administration implements the procedures for medical devices installation effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

5. The program administration implements the procedures for medical devices commissioning effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

6. The program administration implements the procedures for medical devices acceptance effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

7. The program administration improves the policy and procedures for medical devices installation, commissioning, and acceptance periodically.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

6. Training of Users and Operators

1. The program administration has a comprehensive written policy and procedures for medical devices training of users and operators.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

2. The program administration implements national laws and regulations for medical devices training of users and operators effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

3. The program administration implements the medical devices training procedures for medical staff effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

4. The program administration implements the medical devices training procedures for BMET effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

5. The program administration implements the medical devices training procedures for clinical engineers effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

6. The program administration improves the policy and procedures for medical devices training of users and operators periodically.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

7. Monitoring of Use and Performance

4. The program administration has a comprehensive written policy and procedures for the medical devices monitoring of use and performance.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

5. The program administration implements national laws and regulations for the medical devices monitoring of use and performance effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

6. The program administration implements the procedures for the medical devices monitoring of use effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

7. As The program administration implements the policy and procedures for the medical devices performance effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

8. The program administration implements the procedures for the medical devices contracts effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

9. The program administration implements the procedures for recall system for the medical devices effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

10. The program administration improves the policy and procedures for the medical devices monitoring of use and performance periodically.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

8. Maintenance (Corrective, preventive)

1. The program administration has a comprehensive written policy and procedures for medical devices maintenance.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

2. The program administration implements national laws and regulations for the medical devices maintenance effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

3. The program administration implements the procedures of the corrective maintenance for the medical devices effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

4. The program administration implements the procedures of the preventive maintenance for the medical devices effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

5. The program administration provides adequate test equipment for the medical devices.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

6. The program administration implements the procedures of the medical devices calibration effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

7. The program administration improves the policy and procedures for the medical devices maintenance periodically.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

9. Replacement and Disposal

1. The program administration has a comprehensive written policy and procedures for medical devices replacement and disposal.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

2. The program administration implements national laws and regulations for the medical devices replacement and disposal effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

3. The program administration implements the medical devices replacement effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

4. The program administration implements the medical devices disposal effectively.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )

5. The program administration improves the policy and procedures for the medical devices replacement and disposal periodically.

Strongly Agree ( ) Agree ( ) Undecided(Neutral)( ) Disagree ( ) Strongly Disagree ( )