بسم الله الرحمن الرحيم

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Planning for Receiving Donated Medical Equipment

وضع خطة لقبول الاجهزة الطبية الممنوحة

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(قالُوا سُبْحَانَكَ لا عِلْمَ لَنَا إلاّ مَا عَلّمْتَنَا إنّكَ أنْتَ الْعَلِيمُ الْحَكِيمُ)

سورة البقرة (الآية 32)

DEDICATION

This work is dedicated to the two most influential and supportive people in my life my beloved parents who provided me with endless encouragement that I could achieve anything I put my full effort into.

For my Precious brothers and my sister.

For all my friends who palm up their hands praying for me.

Acknowledgment

My grateful thanks to Allah for guiding me and giving me the strength to complete this study, I would like to thank the generous heart and source of wisdom my supervisor Dr. Elias Sidieg.

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Abbreviations:

BME	Biomedical Engineering
MDSOs	Medical Device Safety Officers
IFU	Instructions for use
PCA	patient controlled analgesia
IT	Information technology
PPM	Periodic Preventive Maintenance
PM	Preventive Maintenance
CM	Corrective Maintenance
KPIs	Key of performance indexes

Abstract:

Proper management of medical equipment is important in providing safe and efficient patient care. Healthcare services especially diagnostic, therapeutic and rehabilitation developed due to the development of medical equipment technology. Medical devices become an important part of medicine practice and consider the required condition for medical service quality, effectiveness and safety. Therefore every hospital whether it's large or small contains number of medical devices, the majority of this equipment was purchased, but a portion of this equipments was donated.

This study is guideline to a systematic approach for medical equipment management. Study of the current status in the local hospitals through primary data collection by questionnaire**,** personal interviews and data analysis of the response to the questionnaire was done. Also medical equipment management proposal and forms was designed.

المستخلص:

تعد الإدارة السليمة للمعدات الطبية مهمة في توفير رعاية آمنة وفعالة للمرضى .خدمات الرعاية الصحية خاصة التشخيصية والعلاجية وإعادة التأهيل تقدمت بسبب تطور تكنولوجيا المعدات الطبية . أصبحت الأجهزة الطبية جزءًا لا يتجزأ من ممارسة الطب ، ولكنها تعتبر من الشروط المطلوبة لجودة الخدمة الطبية وفعاليتها وأمانها .لذلك يحتوي كل مستشفى كبيرًا أو صغيرًا على عدد من الأجهزة الطبية ، ويتم شراء غالبية هذه المعدات ، ولكن يتم التبرع بجزء من هذه الاجهزة.

يهدف هذا المشروع إلى اتباع نهج منظم لإدارة المعدات الطبية.

دراسة الوضع الحالي في المستشفيات المحلية من خلال جمع البيانات الأولية عن طريق الاستبيان ، و إجراء مقابلة شخصية ، تم تحليل البيانات من الرد على الاستبيان، كما تم تصميم اقتراح إدارة المعدات الطبية وتصميم النماذج.

Chapter One: Introduction

1.1 General View:

The evolution of the field of biomedical technology has led to the diffusion of an impressive number of medical devices so much that healthcare institutions rely heavily on them to provide diagnosis, treatment and monitoring in patient care. Managing these medical equipment is a formidable task that has to be pursued maximizing the benefits within a highly regulated and cost-constrained environment. Medical engineers are uniquely equipped to determine which policies are the most efficacious and cost effective for a health care institution to ensure that medical devices meet appropriate standards of safety, quality and performance.

1.2 Problem Statement:

Healthcare technology has become an increasingly visible policy issue, and medical equipment management strategies have repeatedly come under the spotlight in recent years. While the need for improved medical equipment management practice has long been recognized and addressed at numerous international forums, health facilities in many countries are still burdened with many problems, including non-functioning medical equipment as a result of factors such as inadequate planning, inadequate acquisition, inappropriate procurement, poorly organized and managed healthcare technical services, and a shortage of skilled personnel.

Donation of healthcare equipment may help to improve the efficiency of health facilities, instances exist where healthcare equipment donations cause more problems than benefits.

1.3 Objectives:

1.3.1 General Objective:

Is to outline a systematic approach for medical equipment management.

1.3.2 Specific Objectives: Is to design forms for :

- Annual planning.
- Procurement plan, Specifications, technical evaluation, acceptance test, case study of replacement.
- Training.
- Maintenance (preventive and corrective maintenance).
- Surplus Assets.
- Streamline the process for managing healthcare equipment donations to improve healthcare services.

1.4 Methodology:

Data was collected from various sources such as former researches and books with respect to medical equipment management.

A questionnaire about medical equipment management, was distributed to ministry of health and national medicine and poisons board and Sudan atomic energy, national medical supplies fund, some companies and hospitals distributed among Khartoum state.

Questionnaires will answer by biomedical engineers and analyze data by google form to obtain a number of results.

1.5 Research Layout:

Chapter one is an introduction to the research, it is define the problem of the research and its objectives. Chapter two illustrates the theoretical background. The literature review was described in chapter three. Chapter four dealing with the methodology for data collection and analysis and result. Chapter five shows the medical equipment management. Chapter six handling with the discussion. Chapter seven is conclusion and recommendations, and finally the references and appendices.

Chapter Two: Theoretical Background

2.1 Biomedical Engineering:

2.1.1 Definitions:

Biomedical Engineering (BME) is the application of engineering principles and design concepts to medicine and biology for healthcare purposes (e.g. diagnostic or therapeutic) [1].

2.1.2 Clinical Engineering:

A clinical engineering is a part of biomedical engineering. A Clinical Engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology [2].

Clinical Engineering is the application of engineering and technology to analyze and provide solutions for the clinical needs of patients. This is a diverse profession covering many areas of health care and clinical engineers often specialize in one aspect of the field. Engineering design, research, development, service management and service delivery are common areas of activity for clinical engineers [3].

As clinical medicine has become increasingly dependent on more sophisticated technologies and the complex equipment associated with it, the clinical engineer has become the bridge between modern medicine and engineering.

Clinical engineering is an interdisciplinary field practiced in a variety of settings and presents a diversity of challenges. The clinical engineer is, by education and training, a problem solver, working with complex human and technological systems.

In the hospital setting the clinical engineer often functions as the technology manager for medical equipment systems. The responsibilities in this setting include financial or budgetary management, service contract management, data processing systems for managing the medical equipment and coordination of service agreements and in-house operations. The hospital-based clinical engineer may also have responsibility for supervision of the in-house maintenance staff, depending on his or her skill set and the structure of the department. Hospital-based clinical engineers also fill other important functions in assuring that the medical equipment is safe and effective.

Clinical engineers have pioneered a new paradigm by forming multidisciplinary groups placed at the point of care to support the application of technology. They in turn work with medical, nursing and paramedical staff to ensure that the care delivered through the application of technology is optimized. The remit of these clinical engineering groups includes the traditional asset management but extends well beyond to include science consultancy, education and training, technology assessment, health informatics, research and innovation.

2.2 The Medical Device:

2.2.1 Definition:

A Medical Device is an instrument, apparatus, implant, in vitro reagent, or similar or related article that is used to diagnose, prevent, or treat disease or other conditions, and does not achieve its purposes through chemical action within or on the body (which would make it a drug) [4].

Whereas medicinal products (also called pharmaceuticals) achieve their principal action by pharmacological, metabolic or immunological means, medical devices act by other means like physical, mechanical, or thermal means.

Medical devices vary greatly in complexity and application. Examples range from simple devices such as tongue depressors, medical thermometers, and disposable gloves to advanced devices such as computers which assist in the conduct of medical testing, implants, and prostheses. The design of medical devices constitutes a major segment of the field of biomedical engineering.

2.2.2 Classification of medical devices:

The FDA categorizes medical devices into one of three classes – Class I, II, or III – based on their risks and the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. Class I devices generally pose the lowest risk to the patient and/or user and Class III devices pose the highest risk.

2.2.3 Medical Device Management:

I. Management System:

Health care organizations should appoint a director or board member with overall responsibility for medical device management. There should be systems in place to ensure reporting of device issues including:

- The effectiveness of the medical devices management system.
- The condition and performance of medical devices including: device failures and issues, utilization, performance, maintenance, repair and calibration history.
- The execution of investment, replacement and disposal plans.

The management structure for medical devices should have clear lines of accountability up to board level. These lines of accountability should be extended, where appropriate, to include general practitioners, residential and care homes, community based services, independent hospitals providing services for patients, managed care providers, Private Finance Initiative (PFI) organizations and other independent contractors. It is important to establish who is accountable, and where there is a need for joint accountability arrangements.

Health care organizations should appoint Medical Device Safety Officers (MDSO) or equivalent. MDSOs replace Medical Device Liaison Officers. Part of the MDSO role is to report adverse incidents to the MHRA and other official agencies. The lines of accountability should include reference to the appointment of such safety officers. Health care organizations should set out a long term approach and objectives for the management of their medical devices, including strategic replacement and Development equipment procurement planning [5].

This should include an overarching medical devices management strategies setting out medium to long term organizational requirements of assets taking account of cost, performance and risk across the entire equipment lifecycle. This strategic approach should also align with the responsible organizations overarching business /Strategic plan.

II. Medical device management group:

Health care organizations should establish a medical devices management group to develop and implement policies across the organization.

It needs appropriate representation from among the following groups of staff:

- Clinical.
- Clinical engineering.
- Clinical trainers.
- Management.
- Infection control.
- Decontamination lead.
- Risk management.
- Maintenance.
- purchasing.
- MDSOs.

Where appropriate, the medical devices management group should include links with specialist groups dealing with specialized medical devices (for example laboratories, radiology and renal dialysis).

The group's role should be to:

- Improve communication about medical devices within the organization.
- Ensure involvement of clinicians, technical staff and users in relation to any proposed changes, including configuration settings relating to devices, where appropriate.
- Define persons responsible for device management tasks, training and safe device operation.
- Define and review the device management policy.
- Review incidents including governance issues relating to medical device management.

2.3 medical device acquisition and selection:

2.3.1 Policy:

Every health care organization should ensure there is a policy or other mechanism for the acquisition and selection of appropriate devices for specific procedures.

Health care organizations should produce and manage the acquisition of medical devices through a multi-year investment and replacement plan. This plan should include a prioritized schedule of all short to long term medical devices requirements and should be monitored against appropriate risk assessment criteria.

The medical devices management group, or other mechanism, should ensure that local policy for the acquisition of medical devices address:

- Safety, quality and performance, as well as all aspects of the acquisition cycle.
- The need to ensure that these election processes takes into account care objectives and priorities of the health care organization, and the needs of the patients.
- The process should consider whole life costs and follow national acquisition policy and recommendations, including any regional or national aggregation of procurement where this results in best value for money.
- The need to ensure that the agreed acquisition requirement takes account of the needs and reasonable preferences of all interested parties, including those involved in use, commissioning, decontamination, maintenance and decommissioning.
- Consumables are cost effective for the life of the device, if applicable. This would include the cost of the device and its maintenance and the life time costs of consumables.
- The mechanism for the acquisition and selection of appropriate devices for specific procedures.

The policy for procuring medical devices should be established in consultation with the professionals who will be prescribing, supplying or using these.

A health care organization could be held responsible, under health and safety law and civil liability in the event that a patient or member of personnel died or suffered personal injury or damage, as a result of in appropriate purchase or prescription of a device.

The MHRA's publication Devices in Practice includes a series of check lists that can help in the purchase, use and maintenance of medical devices and training issues.

2.3.2 Methods of acquisition:

In addition to purchasing and leasing, which are the most common methods of acquisition, there are other ways to acquire medical devices, including: loans from manufacturers or other health care organizations and in-house manufacture.

Hospitals may loan each other devices to avert temporary problems, manufacturers may loan products as part of an evaluation or as an incentive to purchase associated products. In all cases, it must be clear from the outset who is responsible should a problem arise. The medical devices management group should be made aware of any loans.

Some larger clinical/biomedical engineering departments in health care organizations design and build medical devices for their own use. If the devices are supplied to another legal entity, then the Medical Devices Regulations apply. Organizations that manufacture medical devices but do not place them on the market (i.e. they are used only within the organization or legal entity) should, as a matter of best practice, ensure that those devices are manufactured in accordance with the Medical Devices Regulation [6].

2.3.3 Factors to consider before acquisition:

• Agree the requirements for the intended medical procedure and/or needs of the end user.

• Suitability for intended purpose/application by reviewing the manufacturer's description of the intended user, usage and the instructions for use, safety and performance information (including detailed specifications of the medical device), and comparing against the performance specifications contained within the acquisition requirement.

• Safety issues and any limitations on use.

• Software compatibility with archive systems, patient records etc.

• Electronic medical devices which process data needs to be secure, the medical device is validated, as appropriate.

• Ease of use.

Application of usability engineering to medical devices'. Has it been designed to minimize accidental misuse, How easy is it to misuse the device and what precautions are incorporated into the design to guard against misuse. Consider user experience feedback and evaluations from the expected clinical environment [7].

• Evaluate and assess their adaptability of manufacturer's instructions. Instructions for use (IFU) should be comprehensive but intelligible. Overly complex IFU may point to poor design that has not incorporated human usability as a key design goal.
• Availability, type and scope of training. What type of training is available e.g. face-to-face, electronic, e-learning.

• Advice and help. What advice services does the supplier offer and/or what user- help guides are incorporated in or with the system to assist the user with the operation of the device and of its suitability for use for specific procedures.
• Ensuring the operating/environmental conditions of the place where the device will be used are compatible with those of the device.
• Decontamination and disposal procedures, including ensuring the healthcare organization is able to reprocess in line with the manufacturer's instructions (e.g. by trained technicians).The infection prevention team and decontamination lead should be consulted.
• Pre-use set up, testing requirements, installation requirements and commissioning procedure.
• The projected service life of the product and warranty details. In the long run, it could be cheaper to purchase a device which will lastfor10yearsbut costs twice as much as a device designed to last for only3years, as long as maintenance and replacement parts and consumables are available for the life time.
• Whole life costs: acquisition and operational, maintenance and consumable, training, risk, renewal and disposal costs.

• Medical devices may require routine user maintenance, planned preventive maintenance (e.g. by trained technicians) and ad-hoc maintenance, if faults occur. Many require periodic performance checks which may require specialist test equipment. Evaluate the user and planned maintenance recommendations for the device (including frequency and type).Evaluate the ease of breakdown maintenance, particularly in relation to how this will be provided and the response time provided by the supplier for break down maintenance. Ensure that all medical devices can be stored, maintained and serviced in line with the manufacturer's instructions for use. Consider all the costs associated with these before buying.

• Using profiles of existing devices. Before acquiring replacement devices, health care organization should consider whether, with improved equipment management e.g. establishment of equipment libraries, they have sufficient inventory of existing devices to meet requirements.
• Rationalizing the range of models versus diversity.
• Reliability and previous performance.

2.3.4 Choosing correct device:

I. Correct assessment and selection**:**

Assessment of the device taking into account the end user's needs (including aspects ranging from technical operation of the device to comfort and noise) is essential to ensure the correct device is issued. In cases where a specific device would be unsuitable, because the user would not be able to operate it safely, a career may assist the user. The device would therefore also have to meet the needs of the career.

Assessment and supply or fitting of a device can take place in separate institutions and involve different people–prostheses are an example–and the fitter will sometimes need to refer patients back to the prescriber, if the device proves unsuitable. Ensuring that responsibility for choosing the most appropriate device is shared between relevant health care staff, the end user and the fitter can avoid these problems and reduce subsequent delays.

When medical devices are issued, it is essential that any residual risks concerning devices and their accessories are balanced against the anticipated benefits to the user or others. Where risks could not be removed during the design process, subsequent warnings of any residual risk should have been clearly displayed in the user instructions and product markings.

II. Suitability for intended purpose/application:

The device chosen must meet the responsible organization's performance specification, but unnecessary features may be a disadvantage.

Points to consider:

• Whether the device is compatible with other devices and any medicinal products that it is likely to be used with.

• Whether the manufacturer intends the device to be used by those who will be using it.

• Whether the device is appropriate for the intended environment.

III. The procedure for accepting new devices should also identify:

• Any training needs.

• Appropriate planned preventive maintenance and performance checks.

• Technical support needs of users.

• Whether risks associated with using a particular model for the first time have been minimized.

Some devices, such as medical gloves, dressings, catheters and syringes are delivered in bulk packs, so it would be in appropriate to check each one on delivery. For such consumable devices key issues are:

• Expiry dates are clearly show non packaging, as required.

• Appropriate marking for tracing lots, if there is a recall or modification required.

• Instructions and safety information are available, as necessary.

• Packaging is appropriate for storage.

• Environmental conditions for storage are clear.

2.3.5 Safety performance and reliability:

Points to consider:

- CE marking is required for medical devices.
- If there any local knowledge or past history of problems with the device or type of device.
- If MHRA safety publications, manufacturer's advisory notices or other relevant publications identify issues related to the device.
- If other users experienced problems and failures, if the manufacturer provide evidence of reliability from other responsible organizations, and if the manufacturer claim compliance with relevant standards.

2.3.6 Rationalizing the range of models versus Diversity:

Having a variety of models for the same purpose can increase the risk of operator's confusion, leading to misuse and complicating training requirements. Restricting purchase and stockholding to one type of device reduces these risks and can be financially advantageous.

However, reliance on a single model can also cause problems. The chosen model may prove unreliable, or be subject to a manufacturer's recall. Sooner or later, the manufacturer is likely to withdraw the old model, as designs improve or the manufacturer may even cease trading.

There is particular risk of operator's confusion with devices that are superficially similar but have different applications, limitations, settings or operating procedures. If there is a need for different facilities or functions e.g. between infusion pumps for epidural and patient controlled analgesia (PCA) it may be better to choose completely different models.

2.3.7 Installation support devices:

• The installation must be carried out by manufacturer/supplier.

• The required building and utility services, the adequacy of services needs to be established (e.g. the suitability of the electrical or piped gas supply).

• Special decontamination, calibration or other associated equipment needed, complex devices may need specialists to install and commission them.

• The device meet the required IT communication protocols, operating system etc.

• The manufacturer endorse the installation of additional software e.g. virus checker.

2.3.8 Maintenance support devices:

Ensure that devices are regularly checked for functionality prior to use by the user in line with the manufacturer's instructions and throughout the expected life time of the device [8].

Points to consider:

• Service provider must maintain the device.

• The proposed contract or service level agreement deal with continuity of care, for example: on site repair, if needed.

• Alternative devices available to cover periods when the device is being repaired or serviced.

• The response times must be appropriate and guaranteed.

• The proposed servicing intervals, (Also, consider the types of checks and calibrations required between servicing intervals.).
• Spares must readily available for long time.
• Service support guaranteed for long time.
• Information is available from the device manufacturer, e.g. circuit diagrams, preventive maintenance schedules, trouble-shooting guides, repair procedures, parts list, and special tools list.

2.3.9 Documentation and monitoring:

To reduce the possibility of inappropriate devices being purchased or prescribed it is essential that a full performance specification of the entire system is established before any purchases are made. For example, with battery powered device this must incorporate all elements, such as: battery type, charger type, charging process, maintenance and use.
Once the selection process has identified the most suitable medical device, then the final terms and conditions covering all aspects of the acquisition should be agreed by all interested parties and documented. Only then should the contract be awarded, the purchase order raised or the acquisition otherwise be cleared to proceed.
The acquisition should then be managed in accordance with the terms and conditions agreed, and the results of the acquisition and usage experience feedback into any subsequent acquisitions.

2.4 Supplying of medical equipment:

Ensuring that the beneficiaries are actively engaged in all stages of the supplying process**.**
Often the recipients or intended beneficiaries of equipment supplying are neither consulted nor do they take an active role during some or all of the stages of the supplier process, even though they are primary stakeholders in the process. For the purpose of emphasizing the indispensable active role of potential supplier beneficiaries, beneficiaries should thought as "supplier solicitors". Supplier Solicitors are encouraged to be actively involved during all stages of any equipment supplier action. This includes:

- Preparing lists of prioritized equipment needs indicating desired specifications and model preferences.
- Evaluating offers from supply against priority equipment needs and desired specifications and model preferences.

- Preparing and following policies and procedures concerning equipment supplier.
- Preparing and using checklists to ensure that supplier are appropriate and delivered in a timely and efficient manner.
- Sharing with potential supplier the priority lists, policies and checklists concerning medical equipment donations.
- Providing feedback to the supply during the supplier process as well as final outcomes of the supplier. Refusing unsolicited or inappropriate supplier.
- Ensuring that the needs of the end-users and patients are met.

Effective health care providers thoroughly review equipment choices prior to purchase to ensure that the needs of the end-users and the patients are met. Equipment supplier offers should also be given the same level of attention and deliberation, if not more. The criteria listed in the following page, typically used when evaluating equipment purchases, also apply for evaluating equipment supplier offers and can be used supplier solicitors to decide on the suitability of the equipment being considered for supplier.

- **Considerations for existing local markets of medical equipment:**

When local markets for medical equipment are ignored or bypassed, it is likely that the required after-sales support for service, parts and consumables may not be adequately available. Consulting and involving local vendors, where they exist, will help establish beneficial relationships between the users and the vendors of equipment. Additionally, procuring locally helps foster local markets and this will in time reduce the reliance on importing equipment for every purchase, shipping the equipment abroad for service, and paying for expensive travel for service technicians to come from abroad to repair the equipment. Before considering vendors outside of the recipient country, which may not be concerned or in a position to properly support the needs of the users, both donors and supplier solicitors should consider exploring available local sources of medical equipment.

- **Considerations for established procurement systems:**

While many health care systems purchase medical equipment by following established institutional, regional or national guidelines, policies and procedures, supplying many times are not subject to the same level of rigor, which contributes to inadequate equipment being supplied. In the

same manner that purchases need to be properly planned, evaluated, selected, and approved according to governing policies and procedures, so should supplying.

- **Considerations for public health needs**:

Many times considerable attention is given to supplying sophisticated medical equipment, such as lasers and expensive diagnostic imaging machines. However, it is easily forgotten that the majority of medical devices required in any health system are much more basic, and much more useful to public health, such as ophthalmoscopes and eye charts. The lack of appropriate and functioning basic technologies, especially at the primary and first referral levels in remote areas, can limit access to preventive and curative interventions. These basic devices can have a far greater impact on health than much more sophisticated devices. One way to estimate the proper balance of sophisticated and basic equipment is to consider the burden of disease when contemplating the supplying. This analysis goes beyond the hospital or recipient organization to cover multiple levels of care and the locality, region or entire country. Providing sophisticated equipment to operating rooms may have less of an impact on health than supplying far less expensive basic diagnostic and examination equipment for outreach clinics.

- **Inclusion of health facility input when supplying are coordinated at a national level:**

Many supplying are made to the country via the ministry of health or other national bodies. In these situations it is important that the input of the recipient institutions is considered before accepting the supplied device. Without an understanding of the specific needs of the recipient institution, it is very likely that the supplying may not be suitable. National level policies and guidelines for equipment supplying, as well as purchases, need to incorporate as a norm the solicitation of input and feedback from the intended users.

- **Consideration of Special Environmental and Human Resources to Support Equipment:**

Detailed information about the installation, operation, and maintenance of the equipment will enable the supplier solicitor to begin pre installation tasks, including the training of personnel for operation and maintenance.
If pre installation work is required, the recipient should state when the work would be completed. It is desirable that the supplier solicitor provides the supplier with details such as floor plans, architectural drawings and blueprints, which could enable the supplier to identify problems and recommend solutions based on previous experience.
Training of personnel to operate and maintain the equipment is also an important facet of preparation.
If the supplier solicitor or the supplier does not have the technical knowledge to perform the necessary pre-installation or training preparations then proper assistance and consultation by qualified experts is recommended.
After all preparatory requirements have been satisfied, the supplier solicitor can notify the supplier to assemble and package the equipment for shipping.

2.5 Donation of medical equipment:

Donation: A gift given by physical or legal persons, typically for charitable purposes and/or to benefit a cause. A donation may take various forms, including services and new or used goods.

Recipient: A beneficiary of the donated healthcare equipment. Recipient can be a public or private health facility or any third party who will receive a donated healthcare equipment.

Donor: A person, organization, or government who donates healthcare equipment in kind or monetary terms.

Chapter Three: Previous studies

Naila Ahmed , SUST (2016) say: (To design equipment control management program we must first study the situation of some medical equipment departments in our local hospitals and study the current design. The questionnaire was used to illustrate the lake present in those hospitals, economical use of equipment, effective, and staff education. Through analysis and study, we found that there are several problems in public hospitals can be summarized as follows: the ME department can be more useful and more effective if use of the proposed new program, most hospitals didn't have sufficient number of medical equipment, insufficiency of medical devices on MED on some hospitals, and Unavailability of trained medical engineer staff in public hospitals to provide the best services and medical care) [14].

Dr. Ehab Youssef-et al., (2011) United Arab Emirates say :(All devices should carry a clear label indicates the name of the company which is responsible for placement of the product in UAE market, manufacturer in country of origin , local distributor's address or website shows local distributor's name, and contact numbers and address. The local distributors can stick stickers on the outer pack of their products in a way that doesn't conceal any basic or essential information. Any medical device carries no distributor contact information will be liable for confiscation. The sticker should be approved by specific standard [9].

Judith A. Johnson (June 25, 2012) FDA United State of American says: (Medical device regulation is complex, in part because of the wide variety of items that are categorized as medical devices. They may be simple tools used during medical examinations, such as tongue depressors and thermometers, or high-tech lifesaving implants like heart valves and coronary stents. The medical device market has been characterized by including eight industry sectors: surgical and medical instrument manufacturing, surgical appliance and supplies, in-vitro diagnostic products (IVDs, or laboratory tests), electro medical and electrotherapeutic apparatus, irradiation apparatus, dental equipment and supplies, ophthalmic goods, and dental laboratories [10].

Sahar Mohammed (May, 2015) Sudan University of science and technology says: Medical devices play an important role in human being health. Consequently, it is important that there should be unified inspection method for imported medical devices and unify a team of work consisting

of all regulatory authorities in the country. A protocol for inspection of imported medical devices was prepared and explained in figure (flow chart) which was conducted by a questionnaire directed for interested people in charge of regulating and inspecting of imported medical devices. Data was analyzed by using SPSS; in addition to a comparison and by reference to experiences of other countries. Throughout the study, it was turned up that it is important to work as a team for inspection and maintenance of quality of imported medical devices by using laboratories to check through the quality of imported medical devices [11].

Medical Device Regulatory Requirements for Egypt (2007) (The MOH is responsible for the registration and approval of medical devices in Egypt. It does this through the Drug Policy and Planning Center (DPPC) and the Central Administration of Pharmaceutical Affairs (CAPA). The DPPC controls and sets the strategic rules for drug policy, but it also regulates the importation and manufacture of medical devices and instruments. It furthermore controls the registration of medical devices through a specialized committee for study of manufactured and imported medical devices and equipment. This committee comprises leading medical professors (approximately 10) from the specialties of ophthalmology, orthopedics, surgery and cardiology; in addition to professors in medical engineering. Moreover, the committee includes pharmacist managers from CAPA, DPPC and the National Organization for Drug Control and Research (NODCAR) [12].

This committee is responsible for reviewing and approving applications for the manufacture or importation of medical devices and equipment in Egypt. Applicants may be importing companies, manufacturing companies, physicians or individuals. The committee evaluates an application in the light of existing status of device or equipment in question, and whether there is a real need and benefit for Egyptian patients. It then makes a decision regarding the application before the equipment is released from customs or manufactured. As explained below, one further evaluation by another body is often required. CAPA is responsible for registration and issue of final marketing approval for Class III medical devices).

O.Abbas et.al at 2016, designed software program coordinates between regulation bodies that are responsible of importation and inspection of

medical devices to ensure their safety and high quality, also replace paper system with electronic system to facilitate and accelerate the procedures [13].

Chapter Four: Methodology and Results

4.1 Methodology:

The questionnaire was used to illustrate the lake present in those hospitals, economical use of equipment, effective, instruments or staff education & training.

First step was a study the current status in the local hospitals through primary data collection by questionnaire illustrates the real problems and the lake present in those hospitals, economical use of equipment, effective, instruments or staff education & training.

Second step was data analysis which was done by google form. The aim of this step is to focus on the weakness in current medical equipment departments.

Finally, Forms for management of medical equipment was designed.

4.1.1 Survey Field:

The field of these surveys the medical equipment department staff. The criteria of this study included the economical use, medical devices evaluation, staff and training and patient Services. The field survey was used to identify problems and issues of medical equipment department, there were three forms of questionnaire, one for hospitals, another for medical companies, the third one is distributed for ministry of health and national medicine and poisons board and Sudan atomic energy, national medical supplies fund.

There are 24 hospital included in this study and 16 medical company.

4.1.2 Study sampling:

Forms were filled through google form with medical engineer at each hospital, company and ministry of health and national medicine and poisons board and Sudan atomic energy and national medical supplies fund.

The hospital form contained 16 questions, 1 at each hospital.

The companies form contained 12 questions, 1 at each company.

The third form contained 9 questions.

4.1.3 Data collection techniques and tools:

The response to the questionnaires is by google form. It was composed of many questions to evaluate the quality of medical equipment management in hospitals, such questions prepared in accordance with the observation statistical standards for easy to understand and answer questions in a scientific and comprehensive.

4.1.4 Data analysis:

Data analysis implements both descriptive and analytical statistics, which was done by google form.

4.2 Results:

4.2.1 Hospitals:

The questionnaire was distributed to 24 hospitals in different parts of Khartoum state.

1. Awareness about service contract.

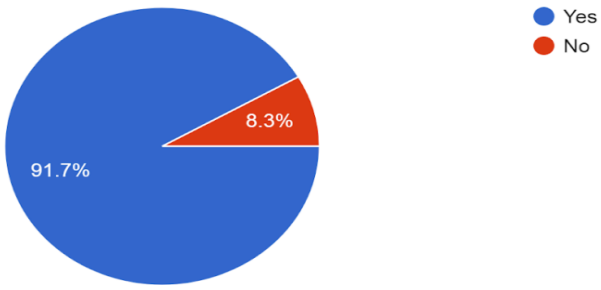

Figure (4.1): Awareness about service contract.

Response to questionnaire shows that 91.7% aware about service contract and 8.3% have no aware about service contract.

2. Needs of assurance \validation of service performance and quality.

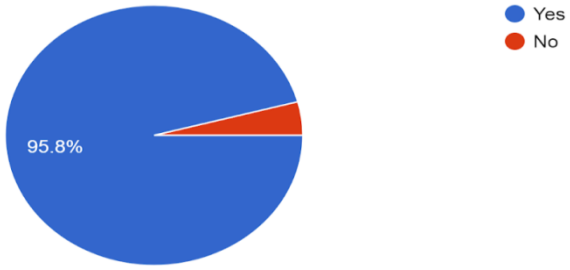

Figure (4.2): Needs of quality assurance.

95.8% said that there is needs of assurance\validation of service performance and quality and 4.2% said no need.

3. Acceptance test.

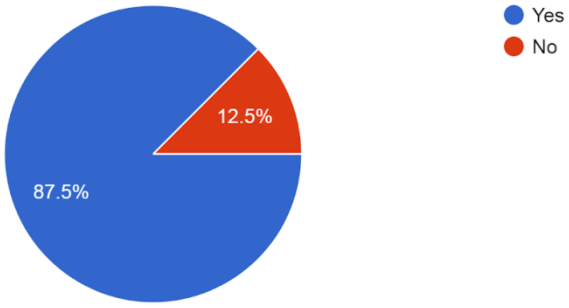

Figure (4.3): Acceptance test.

87.5% apply acceptance test procedure and 12.5% doesn't apply.

4. Training for staff.

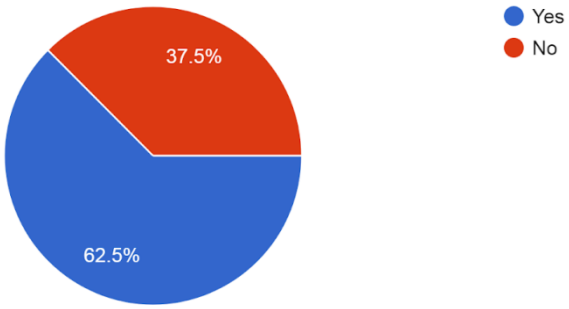

Figure (4.4): Training for staff.

62.5% have received training for staff and engineers and 37.5% have no training.

5. Responding to calling for maintenance.

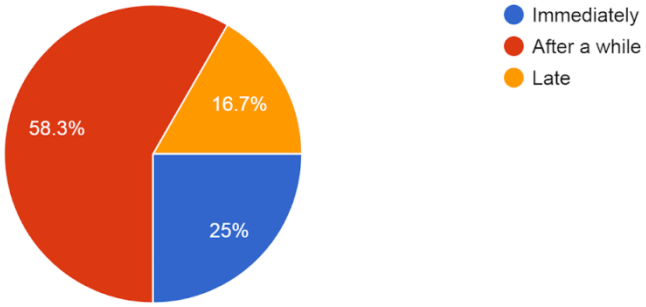

Figure (4.5): Responding to calling for maintenance.

25% said that srvice provider respond to calling for maintenance and 58.3% responed after a while, and 16.7% responed late.

6. Emergency service.

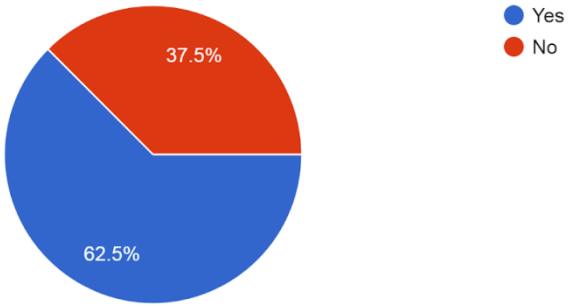

Figure (4.6): Emergency service.

62.5% said that the supplier provide emergency services and 37.5% said supplier doesn't provide emergency services.

7. Clinical\biomedical engineering department.

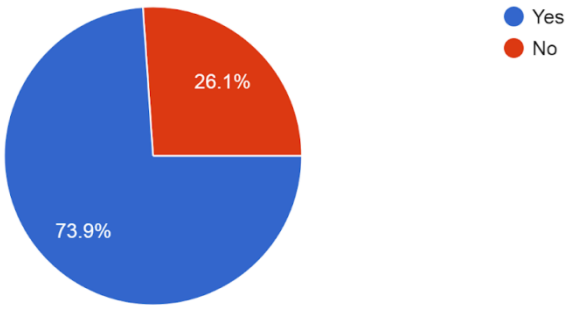

Figure (4.7): Clinical\biomedical engineering department.

73.9% said that they have a well stablished clinical\biomedical engineering department and 26.1% have no BME department.

8. Equipment maintenance staff.

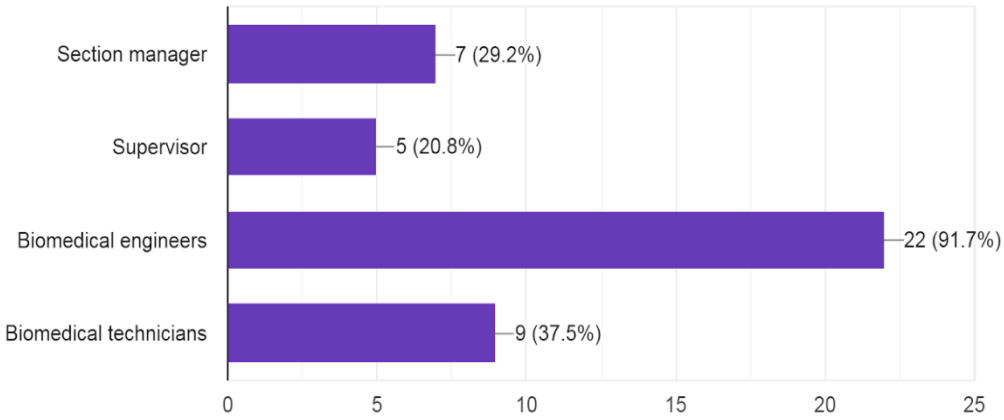

Figure (4.8): Equipment maintenance staff.

29.2% said that section manager is involved in the equipment maintenance program and 20.8% said that supervisor is involved and 91.7% said that biomedical engineers are involved and 37.5% said that biomedical technicians are involved.

9. Inhouse training for technical staff.

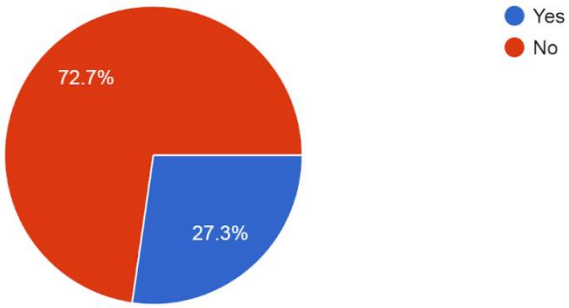

Figure (4.9): In-house training for technical staff.

27.3% said that they provide in-house training for technical staff and 72.7% said they do not provide in-house training.

10. Evaluation of inhouse training for technical staff.

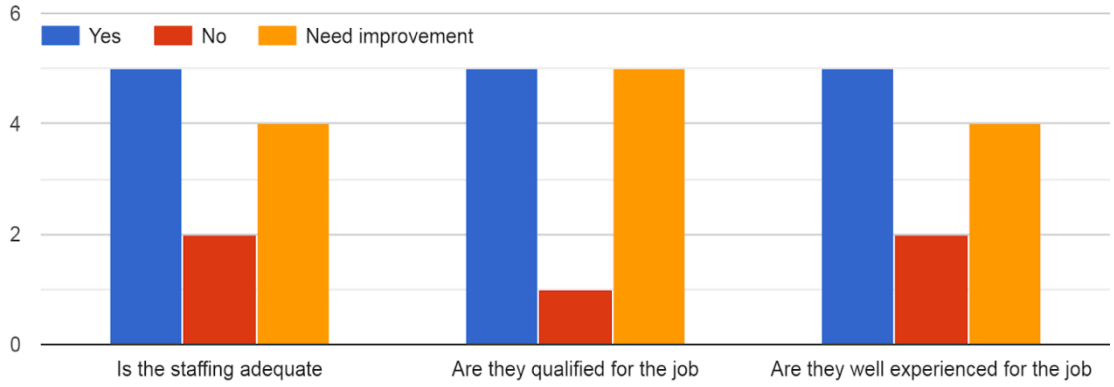

Figure (4.10): Evaluation of in-house training for technical staff.

45.45% said that the staff is adequate and 18.18% said the staff is not adequate, 36.37% said that the staff need improvement.
45.45% said that the staff are qualified for the job and 9.1% said that the staff are not qualified for the job, 45.45% said that they need improvement.
45.45% said that the staff are well experienced for the job and 18.18% said that they are not experienced, 36.37% need improvement.

11. Polices practiced for medical equipment management.

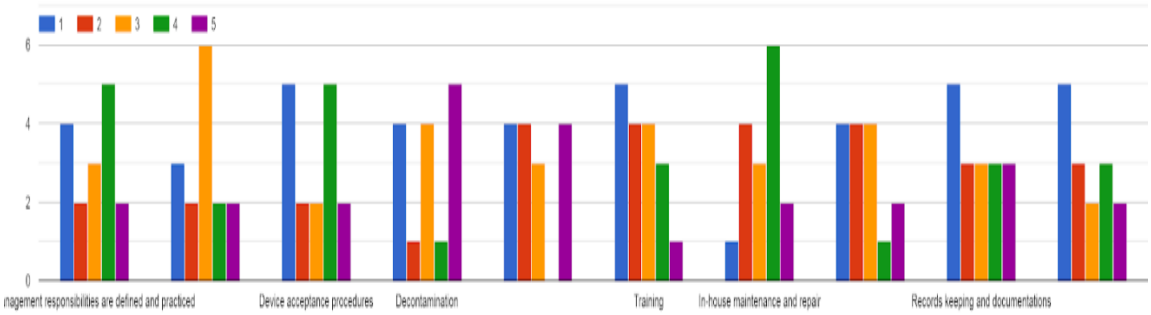

Figure (4.11): Polices practiced for medical equipment management.

12. Planning, acquisition and assessment staff of medical equipment.

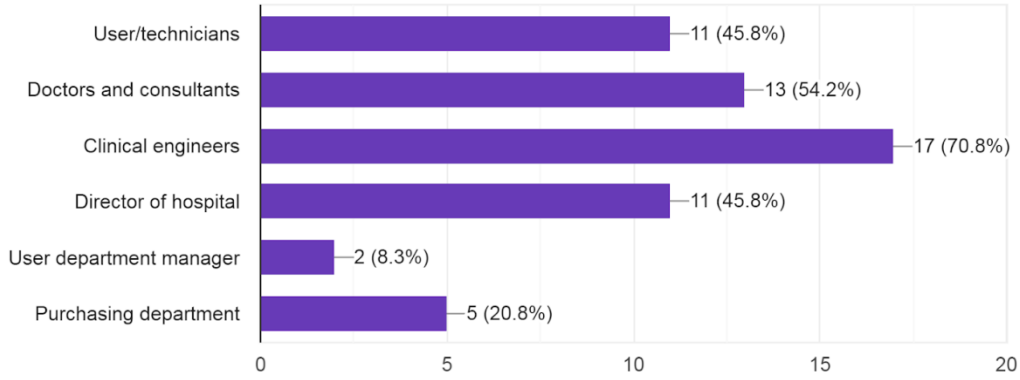

Figure (4.12): Planning, acquisition and assessment staff.

13. Maintenance requirements.

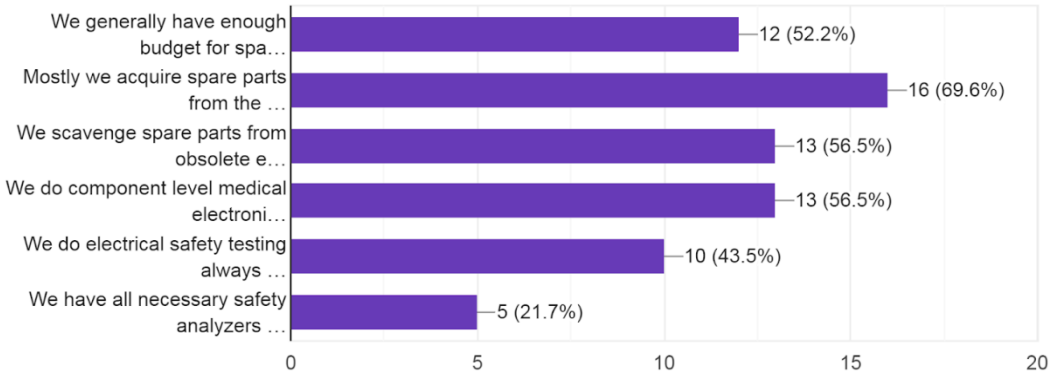

Figure (4.13): Maintenance requirements.

14. Precentage of inhouse repaire for the equipment.

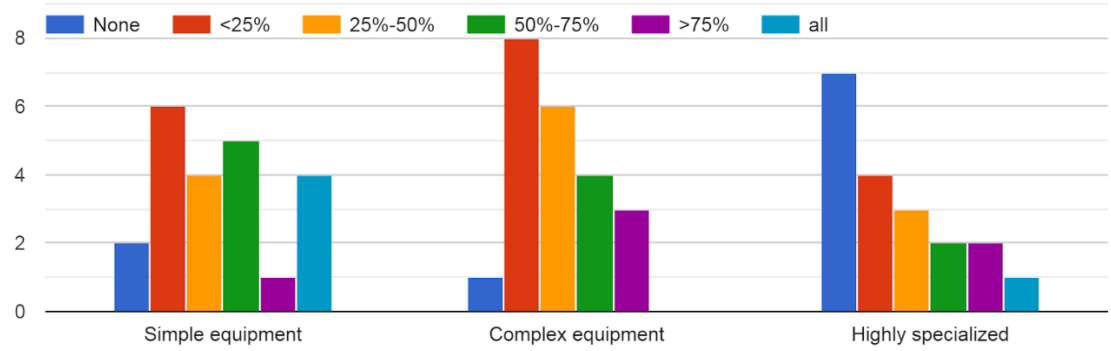

Figure (4.14): Percentage of in-house repair for equipment.

15. Donation of medical equipment.

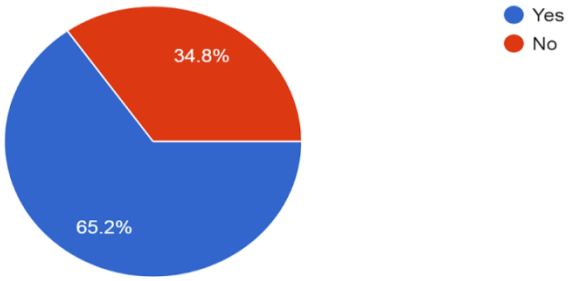

Figure (4.15): Donation of medical equipment.

65.2% received equipments as donation and 34.8% have no donations equipments.

16.Selection of donated equipment.

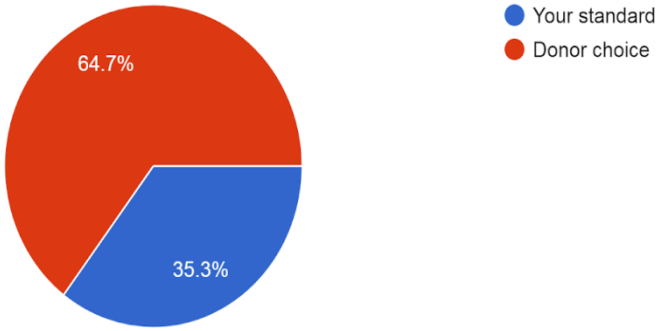

Figure (4.16): Selection of donated equipment.

35.3% choose their donated equipments and 64.7% received the donor choices.

4.2.2 Companies:

The questionnaire was distributed to companies in different parts of Khartoum state and it was found that:

1. Awareness about service contract.

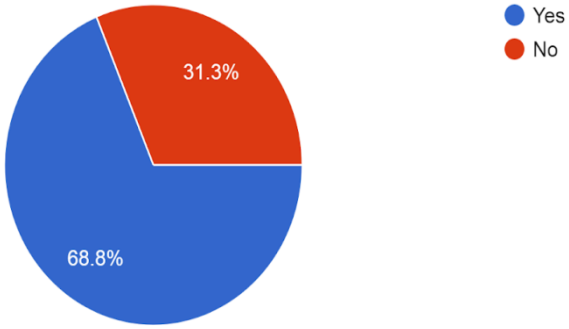

Figure (4.17): Awareness about service contract.

68.8% aware about service contract and 31.3% are not aware about service contract.

2. Needs of third party services.

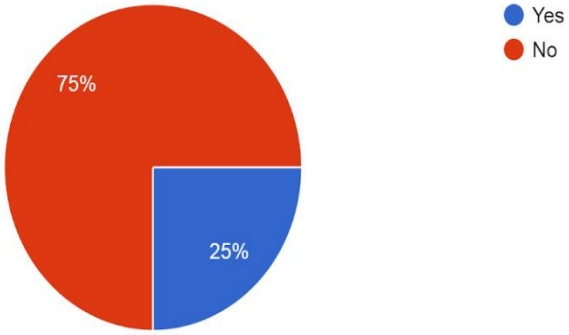

Figure (4.18): Needs of third party services.

25% of service provider said they need third party services and 75% said there is no need for third party services.

3. Purchasing process.

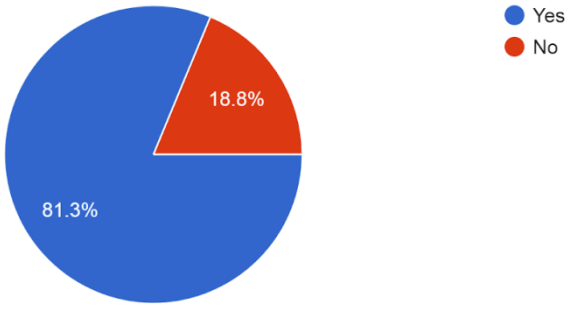

Figure (4.19): Purchasing process.

81.3% said that they have a controlled purchasing process and 18.8% said they have no controlled purchasing process.

4. Inspections used to verify the specifications and requireement.

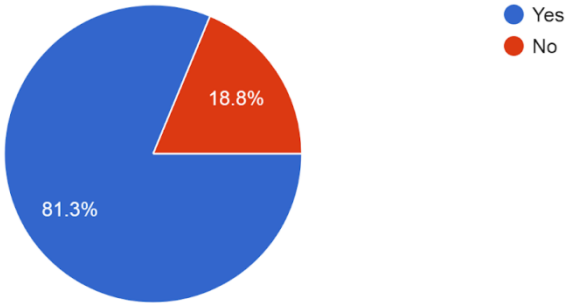

Figure (4.20): Inspections used to verify specifications.

81.3% said that they have a records for incoming inspection maintained and used to verify the specification and requirement and 18.8% said they have no inspections to verify specifications.

5. Advertise the costumers about a new model of the equipments.

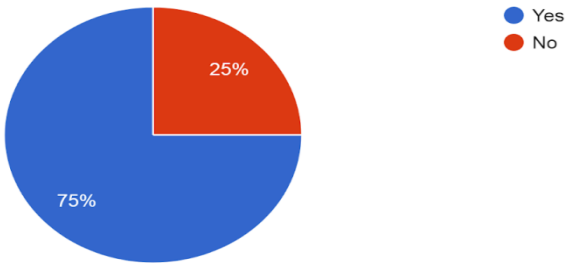

Figure (4.21): Advertise the costumers about new models of devices.

75% said that they advertise the customers about new models of equipment's and 25% said they do not advertise them.

6. Notification of the costumers for new updates in software.

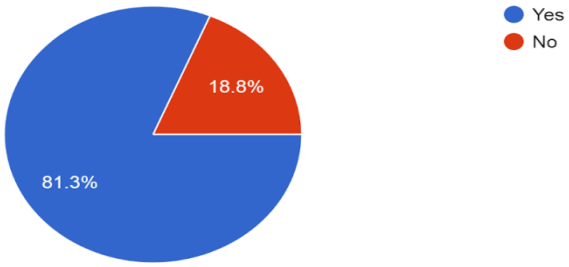

Figure (4.22): Notification the costumers for new updates in software.

81.3% said that they notify the customers for new updates in software and 18.8% said they do not notify them.

7. Devices documentations.

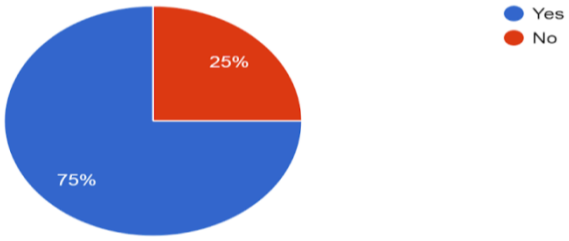

Figure (4.23): Devices documentations.

75% said that they provide documentations for the customers and 25% said that they do not provide it.

8. Installtion and maintenance tools for the costumers.

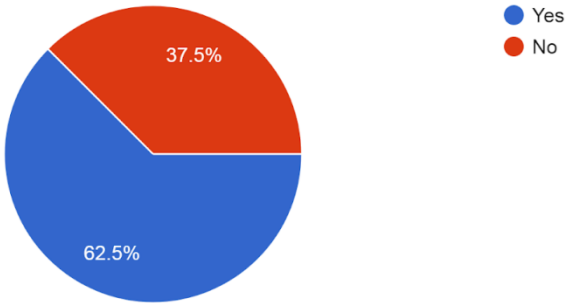

Figure (4.24): Installation and maintenance tools for costumers.

62.5% said that the manufacture provides installation and maintenance tools with the device and 37.5% said they do not have it.

9. Installtionand maitenance tools cost.

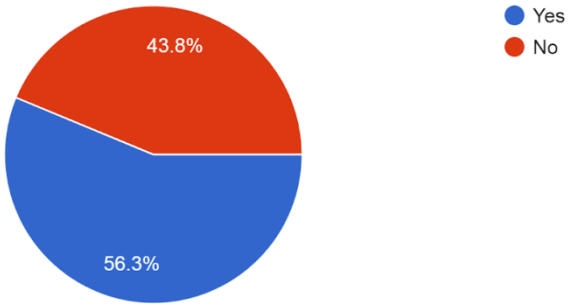

Figure (4.25): Installation and maintenance tools cost.

56.3% said that the manufacturer provide the maintenance tools free and 43.8% said it is costly.

10. Quality control\assurance plan followed services of the equipment.

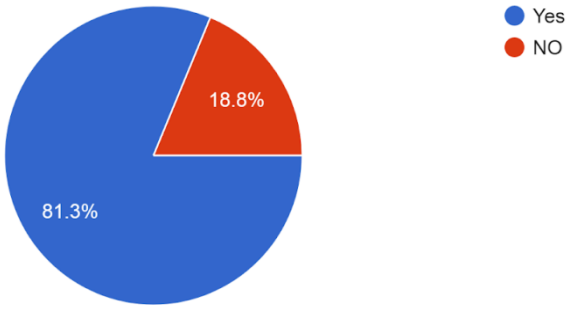

Figure (4.26): Quality control\assurance plan.

81.3% said that there is a quality control\assurance plan followed for each service model\module and 18.8% they have no quality control\assurance plan.

11. Training of technical staff.

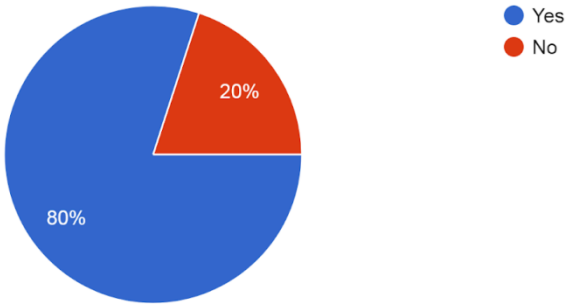

Figure (4.27): Training of technical staff.

80% said that their staff service medical device appropriately trained and 20% said they are not appropriately trained.

12. Donation of medical equipment.

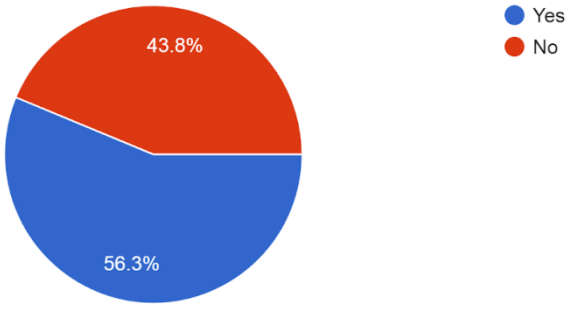

Figure (4.28): Donation of medical equipment.

56.3% said that they received equipments as donation and 43.8% said they do not received donated equipments.

4.2.3 Ministry of health:

The questionnaire was distributed to federal Ministries of Health and national supplies fund, and national medicine and poisons board, and Sudan atomic energy, found a significant interaction of biomedical engineers working there, and it is found that:

1. Medical equipments management units.

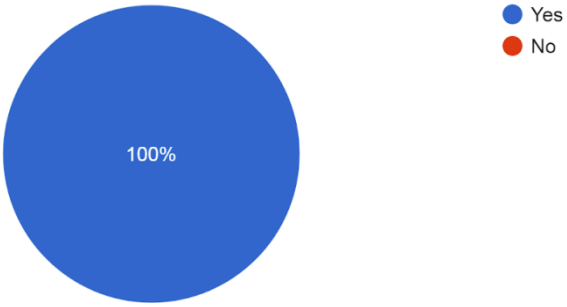

Figure (4.29): Medical equipment management units.

All of them have medical equipments management unit.

2. Medical equipment management software.

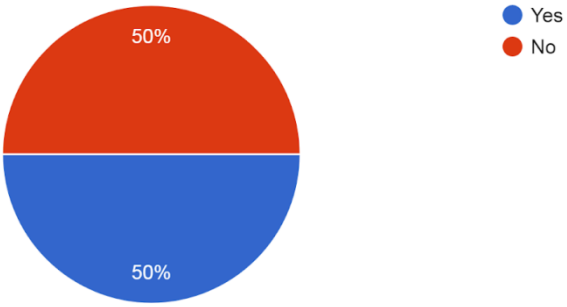

Figure 4.30: Medical equipment management software.

50% said that they have medical equipment management software and 50% said they have no medical equipment management software.

3. Purchasing process.

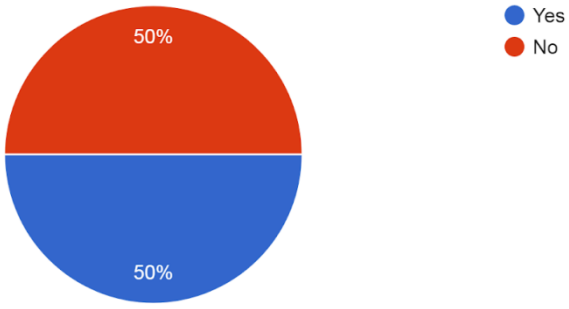

Figure (4.31): Purchasing process.

50% said that they have a controlled purchasing process and 50% said they have no controlled purchasing process.

4. Policy for implementation ot the health technology.

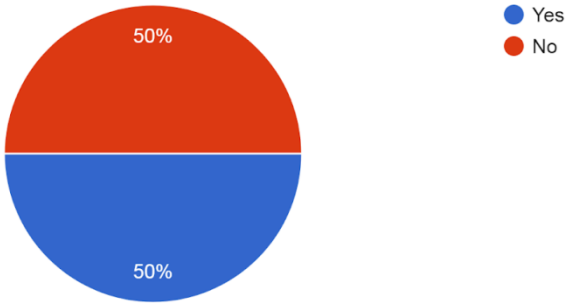

Figure (4.32): Policies for implementation of health technology.

50% said that they have a policy for implementation of the health technology and 50% said they have no policy for implementation of the health technology.

5. National standards of medical devices.

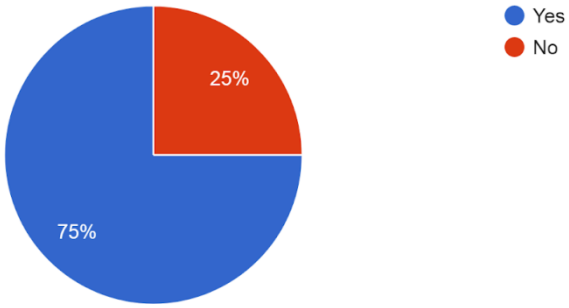

Figure (4.33): National standards for medical devices.

75% said that they have a national standards or recommended list of medical devices and 25% said they have no national standards.

6. National guidelines,policies or recommedations on the procurement of medical devices.

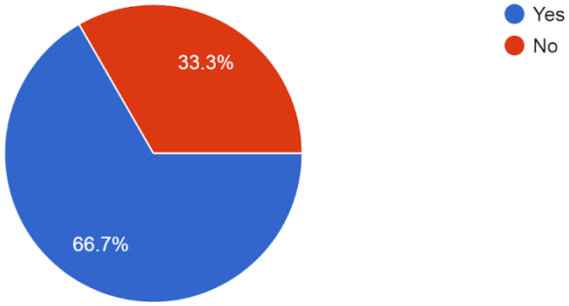

Figure (4.34): National guidelines or procurement.

66.7% said that they have a national guidelines, policies or recommendation on the procurement of medical device and 33.3% said they have no national quidelines.

7. Standard teechnical specifications of medical devices.

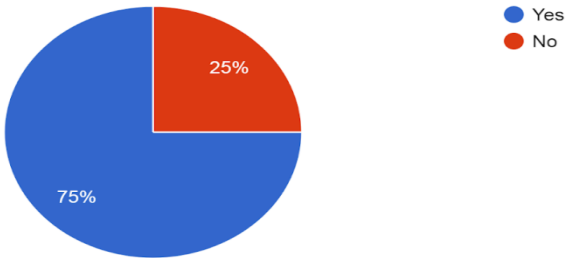

Figure (4.35): Standard technical specification.

75% said that they have standard technical specifications of medical devices to support procurement and 25% said that they have no standard technical specifications.

8. Donatioon of medical equipments.

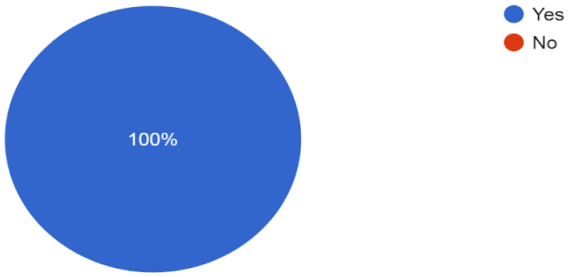

Figure (4.36): Donation of medical equipment.

All of them said that they received equipment's as donation.

9. Selection of donated equipments.

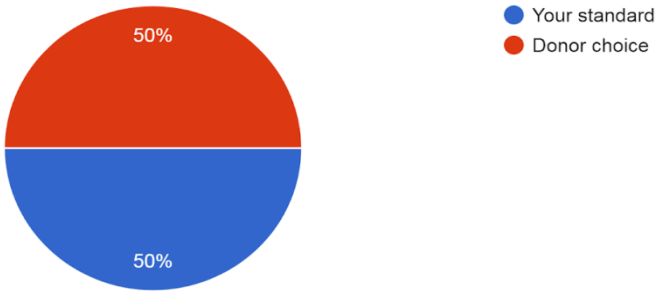

Figure (4.37): Selection of donated equipment.

50% said that they received donor choice equipment's and 50% said that they received their choices of equipments.

4.3 Purchased equipments vs donated equipments:

Every hospital whether it is large or small contains number of medical devices, the majority of this equipments are purchased, but a portion of this equipments is donated so when compare between purchased and donated equipments some points must considered as annual planning, procurement plan, specifications, technical evaluation, acceptance test, training, preventive and corrective maintenance.

Table (4.1) shows a comparison between purchased and donated equipments for the main points of equipments management for three hospitals contain donated equipments.

Table (4.1): Purchased vs donated equipments.

	Purchased	Donated
Annual Planning	0%	0%
Procurement plan	66.67%	0%
Specifications.	66.67%	0%
Technical evaluation.	66.67%	0%
Acceptance test.	66.67%	100%
Training.	66.67%	33.33%
Preventive maintenance	66.67%	0%
Corrective maintenance	66.67%	0%

Chapter Five: Medical Equipment Management

5.1 Medical equipment management proposal:

The scope of the program is to define all biomedical section activities, and responsibilities within hospital facilities. All related policies and procedures govern the work throughout Medical Equipment life cycle (starting from Medical Equipment acquisition, passing through device acceptance, and maintenance, till device retirement). It will ensure reliability, and proper use of medical Equipment by operators, and establishes criteria for identifying, and responding appropriately to Equipment hazards, and recall notices to ensure the safety of patients, and operators.

The objective is to manage the safety, reliable selection, effectiveness, and operation of Medical Equipment used for the care of patients.

5.1.1 Biomedical Engineering Services:

- Biomedical Engineering Section will ensure the proper selection, and acquiring of Medical Equipment by generating Equipment specifications, and perform technical evaluation for any acquisition process that may include new Equipment or spare parts requests.
- Biomedical Engineering Section is to perform maintenance of all medical Equipment throughout hospital facilities which include Preventive Maintenance, Corrective Maintenance, and safety inspection.
- To provide education to personnel to ensure effective application of Equipment, the procedures to follow in case of Equipment failure, and any other information related to it.
- All medical Equipment will be evaluated, where all records of preventive maintenance, corrective maintenance, inspection, and history of Equipment incident will be kept in the Equipment file.
- All new Equipment shall be inspected prior to use to ensure the safety to the patients. Equipment that fails shall not be approved for use until the deficiencies have been corrected.

- All biomedical Equipment failures, and user errors will be investigated, and reported. Report will include date, location of the Equipment, and proper remedy to it.

5.1.2 Staff Structure:

Biomedical Engineering staff composed of Section Manager, Supervisors, Engineers, and Technicians, all are available any time during office hours. One on-call is assigned after working hours to cover the outside working hours. On-call staff will be scheduled.

5.1.3 Incident Investigation:

- In the event a medical Equipment has or may have contributed to Sentinel Event resulting in death or serious injury, the following should be followed:
- Incidents are reported immediately via the hospital reports.
- Biomedical Engineering perform a thorough investigation sequestering Equipment as appropriate, documenting findings, identifying deficiencies that could result in future incidents, and recommending corrective actions. Incident is reported to the manufacturer.

5.1.4 Corrective Maintenance:

By default, each biomedical engineering is responsible for his/her areas. For non-emergency cases, the department using the defective Equipment will be initiate Job order request , and a copy of the job order will be given to the Biomedical Engineering Section, Job order must be completed, and signed by end-user.

5.1.5 Preventive Maintenance:

- It shall be performed in accordance as specified by the manufacturer.(some Equipment require PPM every 3 months and some every 6 months).
- PM work order must be completed, and singed by supervisors.
- All Engineers, and Technicians are assigned to perform PM for the areas they are covering.

5.1.6 Inspection and Acceptance:

Any new medical Equipment, or patient owned Equipment will be inspected, and tested to ensure that it is operating as per manufacturer's specifications, and it's safe for the operators, and patients.

5.1.7 Training and Education:

For new equipment, agent is responsible for providing onsite training to the end user. Where in some cases Manufacturer level of training for biomedical personnel must be provided.

5.1.8 Inventory of Medical Assets:

Biomedical Engineering should control all inventory activities and update inventory once a year. Medical Equipment inventory database with current, and accurate information including Equipment details, location, purchase history, priority levels, and risk factors.

5.1.9 Medical Equipment Maintenance Contract Classification:

- **Class A** – A very specialized medical Equipment requiring service contract agreement that include both of labor, and spare parts. It requires expertise from the manufacturer to perform maintenance services. The allowed time is 48 hrs. for fixing it.
- **Class B** – Any Equipment under contracts of reagents, consumables or labor only. In the case, machines are offered free, where Maintenance is under the care of the dealer with the supervision, and guidance of the Biomedical Engineering Section staff. The allowed time is 48 hrs. for fixing it.
- **Class C** – All other medical Equipment. Maintenance services are performed by BME Section staff members. The allowed time for repairing them is 72 Hrs.

5.1.10 Warranty service:

When an Equipment is still covered under the warranty, and required a maintenance, the Biomedical Engineering Staff member will place a service call to the vendor. Warranty information can be seen on the sticker attached to each piece of Equipment with the date of installation, and warranty period covered.

5.1.11 Biomedical Key of Performance Indexes (KPIs):

- **Response time ratio:** Response time (Hours): It can be described as how fast was the technicians when they engaged their work after malfunctions occurred immediately. However, there is a difference between response times according to the classification of medical devices.

$$Response\ time\ ratio = \frac{time\ taken\ to\ start\ the\ work(hr)}{maximum\ allowed\ time\ for\ the\ equipment} \leq 1 \ldots\ldots\ldots\ldots \quad (1)$$

- **Preventive maintenance to Corrective maintenance ratio:**

It is expected for a machine with a yearly PPM visit to be malfunctioned only a once, therefore the equation will be like:

$$CM\ to\ PM\ ratio = \frac{total\ CM}{total\ PM} \leq 1 \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots \quad (2)$$

The ratio must be calculated for the same type of Equipment,

and average is taken for the group numbers of the identical equipment. The value of 1 is the maximum allowed given ratio.

- **Maintenance rate:** It can be described as the total investment made for a specific asset after purchasing which means it is no sense to spend the same amount of money used for purchasing an asset for maintenance costs.

$$\text{Maintenance rate} = \frac{\text{maintenance cost(labor+spareparts)}}{\text{purchasing price}} \leq 80\% \ldots\ldots\ldots\ldots\ldots\ldots \quad (3)$$

- **Working efficiency %:**

It can be described as the interruption of the service given to the user.

$$Working\ efficiency\ \% = 1 - \frac{down\ time}{up\ time} \geq 98\% \text{.....} \quad (4)$$

5.1.12 Quality Control:

- It is to ensure that all Equipment are functioning, and well maintained in accordance with manufacturer's specifications, and properly calibrated for both CM, and PM.
- It is to ensure that all Equipment is evaluated by applying BME KPIs, and replacement criteria.
- It is to ensure the best inventory control, for newly coming Equipment, running equipment, and surplus assets with proper filing to all documentations.
- It is to ensure the best selection of Medical device, and spare parts.
- It is to ensure that all operators, and end-users are giving adequate operating instructions, and technical support.

5.1.13 Equipment Replacement Criteria:

- For variety of reasons, the services of older medical Equipment, and devices have come to an end, and replacement for such Equipment must be in place. Biomedical Engineering Section has developed several criteria for evaluating old Equipment, and systems. (There is a Case Study form for each equipment to process the replacement).

- Criteria for evaluating capital medical Equipment for replacement is:
  1. The device is damage, and beyond economical repair.
  2. Clinical or technical obsolescence.
  3. Absence of manufacturer/supplier support (e.g. Non–Availability of spare parts accessories).
  4. Possible benefits of new model (feature, usability, more clinically effective)
  5. To lower the running cost.
  6. Device usage is not reliable (KPIs).
  7. Non availability of correct parts &accessories.
  8. Lifecycle of medical equipment (Age).

5.2 Donation of medical equipment:

Many developing countries are increasingly dependent on donor assistance to meet the equipment needs of their health care systems. However, because not all important parameters are taken into consideration, donations sometimes do not achieve their intended objectives, and could even constitute an added burden to the recipient health care system. There is therefore a need to improve the process of equipment donation, to the mutual benefit of both donors and recipients.

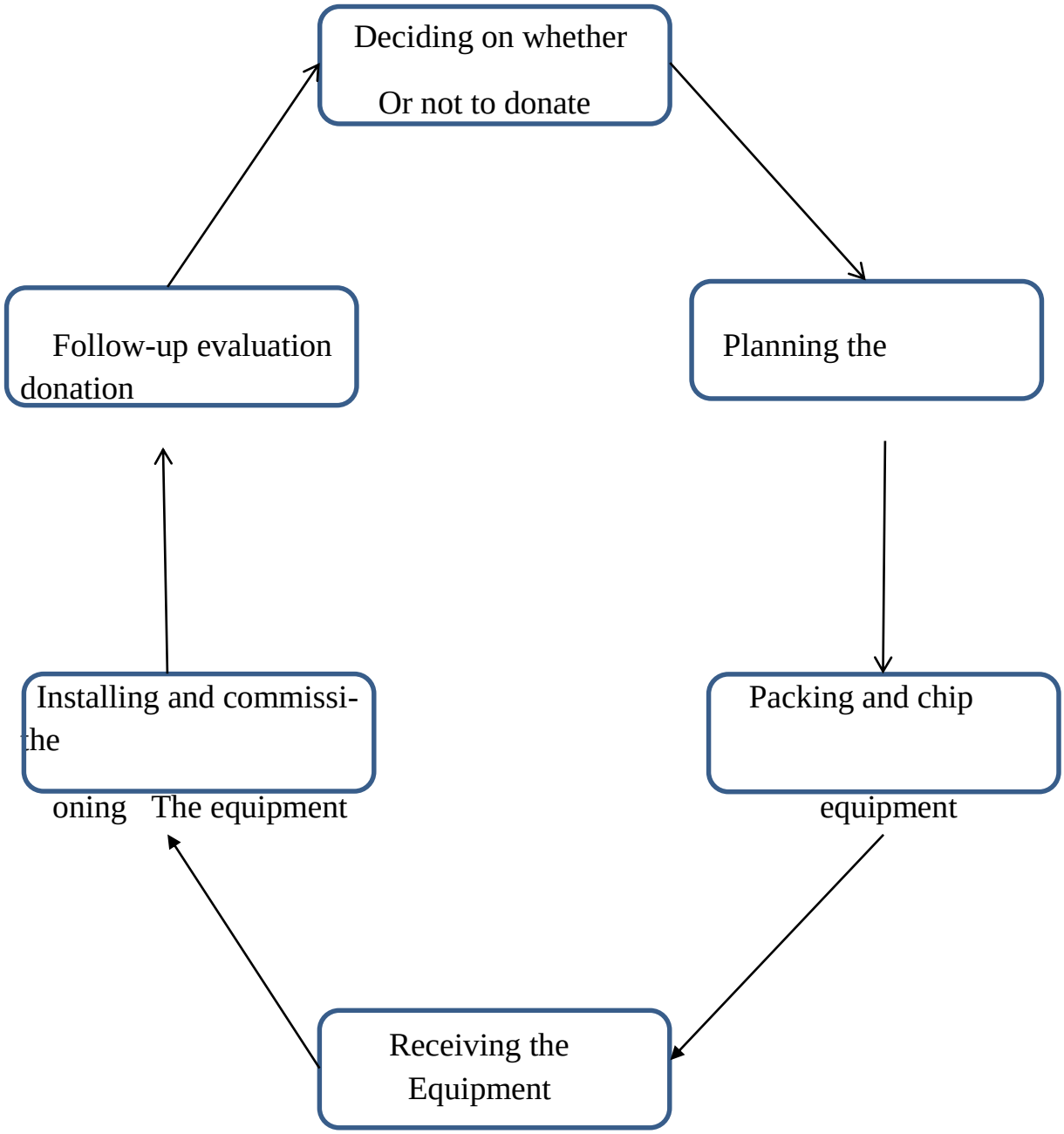

Figure 5.1: Cycle of medical equipment donation

5.2.1 Deciding whether or not to donate:

The donation process can be initiated by a donor, recipient, or third party. Donated healthcare equipment must be at high quality and has maintenance support, spare parts and consumables, and after sale services. Also must be ensure availability of training on proper use of the healthcare equipment and harmonization and sustainability with existing equipment. When deciding whether or not to receive a donation, the recipient and the donor shall ensure the following criteria are met:

- The healthcare equipment responds to an identified need.
- The healthcare equipment is appropriate to the setting of the health facility (i.e. Climatic and environmental conditions and adequate infrastructure).
- The healthcare equipment meets existing safety and performance specifications provided by the manufacturer and promulgated by international bodies, such as European conformity (CE) or the Food and Drug Administration (FDA).
- The healthcare equipment is affordable and cost-effective, including operation and maintenance costs in term of spare parts and consumables.
- The healthcare equipment is user-friendly with updated upgradeable software in one of the official languages.
- The equipment has a sufficient remaining life span (at least 70% of the life span provided by equipment manufacturer).
- The healthcare equipment conforms to the recipient's policies, plans and guidelines.
- The healthcare equipment can be affordably and safety disposed of in accordance to the national policies and guidelines.
- The decontamination of healthcare equipment is easily performed by end users with affordable and accessible cleaning supplies for infection control.
- The healthcare equipment can be maintained locally (i.e. the availability of human resources with the needed expertise).

All donations has to follow the above criteria. The recipient should not feel obliged to accept a donation that does not fulfil the above prescribed requirements.

Further, additional caution should be taken when considering donations of complex equipment requiring specialized training to operate and maintain, a strong supply chain for consumables, and significant changes to infrastructure for proper functioning of the equipment.

Recipient specific responsibilities:

- Conduct needs assessment of existing healthcare equipment to identify gaps to respond to the national policies and strategies.
- Ensure appropriateness of equipment in terms of health facility level, running costs, technical design and technology (affordable cost, low energy consumption, standardized with other equipment, simplicity of operation, minimal number of accessories required, and availability of necessary operating supplies, particularly disposable).
- Provide comprehensive specifications for needed equipment.
- Conduct a critical assessment of the healthcare equipment to ensure quality and safety and local and international standards and requirements are met.
- Ensure that all resources needed are available at health facility, including needed expertise to operate and maintain the equipment.
- Ensure the costs of transport to the health facility, custom duties, and any other charges associated with importation are fully funded either by the donor or recipient.
- Ensure the following requirements are met for proper use of healthcare equipment: installation location, safety requirement (such as shielding), accessibility, floor loading capacity, space and electrical power (voltage, frequency, phase, and dissipation), needed water volume and pressure (and drainage), and environmental conditions.
- If pre-installation work is required, the recipient should state when the work will be completed.

Donor specific responsibilities:

- When the donation process is initiated by the donor, a letter of intent must be submitted to the ministry of health to ensure healthcare equipment specifications conform to the ministry of health equipment guidelines.
- When the donation process is initiated by the recipient, the donor must receive the official request for the donation from the ministry of health.
- Conduct assessment visit to the recipient facility prior to the donation.
- Ensure the healthcare equipment is fully operational at the system level. Used equipment should be fully rebuilt or reconditioned.
- Ensure that the healthcare equipment complies with the technical specifications provided by the recipient.
- Ensure availability of a full set of technical and manual documents (installation, operation, maintenance and repair manuals).
- Provide a list of and supply sufficient consumables and spare parts to last one year at a minimum.
- Provide details for manufacturers or authorized dealers to source spare parts and consumables.
- Ensure commitment from manufacturer to provide technical support to the recipient, including troubleshooting, repair and maintenance assistance.
- Specify when the healthcare equipment was originally purchased, at what cost, its expected life span and for how long it has been in operation.
- Provide document of warranty (guarantee) for the replacement or repair of faulty equipment, if new.
- Ensure proper packaging of the equipment to minimize damage during transportation.
- Provide competent and qualified engineer to install and commission equipment.
- Define staff and training requirements for users and technicians.
- Support needed maintenance of the healthcare equipment for at least one year.

- Conduct evaluation visit to the recipient facility after the donation depending on the context of the healthcare equipment.

5.2.2 Planning the donation:

When the donor and recipient are confident that they have the resources required to meet the above requirements, they can begin to plan the donation together.

At this stage,

- The recipient should have completed the needs assessment and developed the technical specifications of the needed healthcare equipment.
- The recipient and donor should have had a clear and honest discussion about what they are able to contribute.
- The donor and recipient must develop a clear agreement that outlines the term of the donation, including the costs and risks incurred by both stakeholders.
- The signed agreement must clarify and include a project plan including activities and tasks, required resources, outputs, responsible stakeholders, conditions, timeline and how the healthcare equipment will be supplied, including involving local vendors where applicable.

Local vendors should be involved when possible because:

- When local markets for healthcare equipment are ignored or bypassed, it is likely that the required after-sales support for service, parts, and consumables may not be adequately available.
- Consulting and involving local vendors will help to establish beneficial and sustainable relationships between the users and the vendors of equipment and build the local technical capacity.
- Purchasing locally will help boost the Sudanese economy.

5.2.3 Packaging and shipping the healthcare equipment:

The donor should ensure the proper packaging of the healthcare equipment, as the equipment is likely to be in long periods of transit. Therefore, the packaging must be strong and sturdy to withstand rough handling and to minimize damage during transportation. The equipment packaging should include:

- A clear packaging list identifying all components, indicating the contents of each numbered carton by quantity, serial number, weight and any special storage conditions.
- Installation, operation, maintenance and repair manuals, if available.
- Procedures or recommendations for periodic inspection, maintenance and calibration to ensure that the equipment is maintained in a safe and effective operating condition.

Further special care in packaging should be taken for the following cases:

- Healthcare equipment that may contaminate should be properly packaged, shipped, and accompanied by the certificate of decontamination.
- Radioactive sources should be removed and properly packaged in special shipment containers (with radioactive marking on outside).
- Fragile healthcare equipment should be packaged with great care and with marking on outer packaging.

5.2.4 Receiving the equipment:

When the recipient receive the equipment, the recipient should conduct the following inspections:

- The reception team should inspect all containers and contents for damage and should verify that the contents are intact and nothing is missing.
- Upon arrival at the health facility, the reception team checks if all required documents to receive the healthcare equipment are supplied and ensure that the equipment meets all the technical specifications agreed on in advance.

If the equipment is technically complex, the recipient should ensure that the unpacking and verification are done by a technically competent and knowledgeable person to reduce the risk of damage.

If the healthcare equipment does not pass the inspection stages, the recipient should inform the donor of the issue resolution. If the donor cannot find a solution, the recipient has the right to reject the donation, and the donor will bear all the costs related to the return or disposal within an agreed timeline based on agreement.

The transportation cost of the equipment within the country will be covered either by the donor or recipient depending on the agreement.

5.2.5 Installing and commissioning the donated healthcare equipment:

The donation agreement signed between the two parties should state the responsibilities of each party, including installation and commissioning of the healthcare equipment. This work should be done by a competent and qualified engineer according to the instructions from the manufacturer.

Commissioning includes verification of proper and safe operation, which must be performed prior to clinical use.

Once the equipment is installed, the recipient should implement a program of periodic inspection, maintenance and calibration to ensure that the equipment is maintained in a safe and effective operating condition for its remaining life span.

To ensure the equipment is used in the most effective way, the donor is required to train the end users and engineers on how the equipment should be properly used and maintained according to manufacturer instructions and based on the terms of agreement.

Final acceptance should be confirmed by the recipient to the donor once the equipment is installed and fully functioning.

5.2.6 Follow-up Evaluation:

The mere supply of equipment does not guarantee a positive impact on healthcare delivery and health outcome. Following installation and commissioning of the equipment, the donor and the recipient should assess the level of operational success or failure of the equipment donated.

This assessment fosters communication between the donor and recipient, encourages the continued support of the donor, and encourages both parties to learn and improve from previous experience.

The following success indicators for the follow-up evaluation should be defined in the agreement between the donor and the recipient and based on the context of the equipment:

- Functionality of equipment.
- Ability of end users to properly operate equipment.
- Ability of engineers or technicians to properly maintain and fix equipment.
- Availability of spare parts and consumables.

Further it is critically for timing of the follow up evaluation to be defined in the agreement between the donor and recipient.

Chapter Six: Discussion

In today's environment of accelerating cost, the need to improve the management of medical equipment is more important than ever.

To design equipment control management proposal first the study of the situation of some medical equipment departments in our local hospitals and study the current status.

The questionnaire was used to illustrate the lake present in those hospitals, economical use of equipment, effective, and staff education.

Through analysis and study, we found that there are several problems in hospitals can be summarized as follows: most hospitals didn't have sufficient number of medical equipment, , and Unavailability of trained medical engineer and staff in public hospitals to provide the best services and medical care.

Donor devices also had been taken into account so that there are some hospitals receive equipment from donors but the problem of that equipment depend on the donors choices and there are no standard for that.

Survey of donation equipment involve three hospitals among Khartoum state as follow:

One of those hospitals contain number of donated equipment, six baby incubators installed by engineers in the hospital with no local agent so that one of them need service with electronic board and no spare part available for it. Also the hospital have three ventilators enter as used donation with no local agent and one of them need electronic board and another one gives false total volume so that two of them are out of service.

A second hospital also has three used ventilators with no local agent, one of them is out of service needs spare part.

A third hospital all of its equipment's are donation from japan with 113 items, some of those equipment have local agent but some of local agents are respond late for installation of the equipment's, some of the equipment's has no local agent but the organization in japan named agent in Sudan responsible from the rest of the equipment's but one of those equipment need service but no spare part available in stock of the named responsible agent and there are no other backup for that equipment. The engineers in

that hospital have no any documentation for installation or warranty period of those equipment.

Chapter Seven: Conclusion and Recommendations

7.1 Conclusion:

The Medical Equipment Management Plan defines the mechanisms for interaction and oversight of the medical equipment used in the diagnosis, treatment, and monitoring of patients. The related policies and procedures govern activities from selection and acquisition to incoming inspection and maintenance of medical equipment.

The administration and oversight of medical equipment management is primarily the responsibility of Clinical Engineering.

This proposal also can Improve employee knowledge of medical equipment requirements and support the routine operational needs of equipment users, Participates with pre-purchase equipment selection and new product evaluations, Manage and track all maintenance requirements, activities, and expenses required to service, repair, and keep operational all equipment included in the plan, Develop and manage all aspects of a comprehensive maintenance program and related quality assurance activities that take into account equipment function, and maintenance requirements, and how to deal with donated equipment.

7.2 Recommendations:

- It is recommended that any donated equipment must follow the cycle of medical equipment's donation in this study.
- The local vendors should be involved because the required after-sales support for service, parts, and consumables may not be adequately available.
- Advance training for both engineers and operators.
- Braintrust to plan for donated equipment; permission and license (authorization).

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Appendix (A)

Sudan University of science and technology

Questionnaire about Medical Equipment Management

Q1: Is there awareness about service contract procedure?

Yes ☐ No ☐

Q2: Do you need assurance\validation of service performance and quality?

Yes ☐ No ☐

Q3: When buying a medical device do you test and examine functionality before use? (Acceptance test)

Yes ☐ No ☐

Q4: Dose the provider gives an appropriate training for the staff (Engineer\Operator) that uses the devices?

Yes ☐ No ☐

Q5: The service provider response to calling for maintenance:

Immediately ☐ After a while ☐ Late ☐

Q6: Dose the supplier provides emergency service?

Yes ☐ No ☐

Q7: Do you have a well-established clinical/biomedical engineering department?

Yes ☐ No ☐

Q8: Which of the following staff do you have in the equipment maintenance program:

Section managers ☐

Supervisors ☐

Biomedical engineers ☐

Biomedical technicians ☐

Q9: Do you provide in-house and overseas training to your technical staff for their professional development?

Yes ☐ No ☐

Q10: If yes, then please tick which is applicable:

	Yes	No	Need improvement
Is the staffing adequate?	☐	☐	☐
Are they qualified for the job?	☐	☐	☐
Are they well experienced for the job?	☐	☐	☐

Q11: Which of the following policies are developed and practiced at your hospital concerned with medical equipment management, 5 being the best and 1 being the least practiced:

	1	2	3	4	5
Management responsibilities are defined and practiced	☐	☐	☐	☐	☐
Acquisition policy	☐	☐	☐	☐	☐
Device acceptance procedures	☐	☐	☐	☐	☐
Decontamination	☐	☐	☐	☐	☐
Disposal and retirement of medical equipment	☐	☐	☐	☐	☐
Training	☐	☐	☐	☐	☐
In-house maintenance and repair	☐	☐	☐	☐	☐
Utilization of equipment management software	☐	☐	☐	☐	☐
Records keeping and documentations	☐	☐	☐	☐	☐
Adverse incidents reporting	☐	☐	☐	☐	☐

Q12: Who are generally involved in the planning, acquisition and assessment of medical equipment? Tick which is most applicable:

User/technicians ☐ Doctors and consultants ☐

Clinical engineers ☐ Director of hospital ☐

User department manager ☐ Purchasing department ☐

Q13: Check all that apply:

We generally have enough budget for spare parts ☐

Mostly we acquire spare parts from the manufacturer ☐

We scavenge spare parts from obsolete equipment ☐

We do component level medical electronics repair ☐

We do electrical safety testing always before deployment ☐

We have all necessary safety analyzers and test equipment ☐

Q14: How much of your equipment is repaired in-house (as opposed to externally)?

	None	<25%	25%-50%	50%-75%	>75%	all
Simple equipment	☐	☐	☐	☐	☐	☐
Complex equipment	☐	☐	☐	☐	☐	☐
Highly specialized	☐	☐	☐	☐	☐	☐

Q15: Is there any medical equipment enter as gift or donation?

Yes ☐ No ☐

Q16: If yes, are they order with:

Your standard ☐ Donor choice ☐

Sudan University of science and technology

Questionnaire about Medical Equipment Management

Q1: Is there awareness about service contract procedure?

Yes ☐ No ☐

Q2: As an equipment supplier do you need third party service?

Yes ☐ No ☐

Q3: Is there a controlled purchasing process in place to ensure purchased product, material and\or service conforms to requirement?

Yes ☐ No ☐

Q4: Are there records for incoming inspection maintained and used to verify the specification and requirement?

Yes ☐ No ☐

Q5: Do you advertise to your costumers about new models of devices?

Yes ☐ No ☐

Q6: Do the company notify the costumers for new updates in the software?

Yes ☐ No ☐

Q7: Are the devices documentations (Operational, service) regard to the user?

Yes ☐ No ☐

Q8: Dose the manufacture provides installation and maintenance tools with the device?

Yes ☐ No ☐

Q9: Do they provide it freely?

Yes ☐ No ☐

Q10: Is a quality control\assurance plan followed for each service model\module?

Yes ☐ No ☐

Q11: Are your staff service medical device appropriately trained?

Yes ☐ No ☐

Q12: Do you sell an equipment for donors?

Yes ☐ No ☐

Sudan University of science and technology

Questionnaire about Medical Equipment Management

Q1: Are there any medical equipment management units with professionally trained biomedical\clinical engineer or technician?

Yes ☐ No ☐

Q2: Is there any medical equipment management software used in public institutions in our country?

Yes ☐ No ☐

Q3: Is there a controlled purchasing process in place to ensure purchased product, material or\and service conforms to requirements?

Yes ☐ No ☐

Q4: Is there a policy for implementation of the health technology?

Yes ☐ No ☐

Q 5: Are there national standards or recommended list of medical devices for different types of the health care facilities (health center\district\regional\or specialty hospital)?

Yes ☐ No ☐

Q6: Are there any national guidelines, policies or recommendation on the procurement of medical device?

Yes ☐ No ☐

Q7: Are there standard technical specifications of medical devices to support procurement or supplying the publically available?

Yes ☐ No ☐

Q8: Is there any medical equipment enter as gift or donation?

Yes ☐ No ☐

Q9: If yes, are they order with:

Your standard ☐ Donor choice ☐

Appendix (B)

Preventive Maintenance Report Form:

Preventive Maintenance Report NO:00000								
Date	DD	MM	YY	Location				
Instrument	ID Code		S/N	Cycle Counter	SRV	D	WC	H.G
Engineer	Name			Signature				

- Preventive maintenance carried out:
  - Clean SRV
  - Clean Trap Chamber
  - Clean Transducers
  - Clean Waste Chamber
  - Clean Rinse Cup
  - WBC & RBC Clog Adjustments
  - HGB Blank Adjustment
  - Run Quality Control

Work Pending: Recommendations:	Dept. Head Name: Dept. Head Signature:

Annual Planning Form (for action plan of medical equipment management)

Planning item	Schedule for Planning Work	Planning Completion Date
1 Medical equipment committee meeting 2 Inventory update schedule 3 Update inventory analyses schedule (Update equipment development plan, consumable list, spare parts list) 4 User training schedule 5 Daily maintenance monitoring schedule 6 Planned Preventive Maintenance Schedule 7 Decommissioning work		

Planned by (date)……..

Checked by (date) ……

Planning work completion checked by (date)……..

Biomedical Engineering Case study of replacement program

Description	Model	Year Purchase	Age(Years)	Manu.	PM Freq (days)	Number of CM(last 3 year)	Unit Cost	Maintenance Cost

Conclusion:

The above equipment are recommended to be included to replacement program due to the following criteria:

1. The device is damage or worn-out beyond economic repair	☐	2.Its reliability (check service history)	☐
3.Clinical or technical obsolescence	√ ☐	4.Non availability of correct parts & accessories	☐ √
5.Absence of manufacturer suppler support	√ ☐	6.Functional but hazardous	☐
7.Possible benefits of new model (Feature, usability, more clinically effective)	√ ☐	8.Lifecycle of medical equipment (Age)	√ ☐
9.To lower the running cost	√ ☐	10.User opinions	☐ √

Prepared by: _____ Approved by: _____

Medical Affairs Director Biomedical Manage

Equipment Profile

RC Tag NO.	**Location**
Model	**Serial NO.**
Specification: Note: Department: Maintenance Section:	
Manufacturer: Vendor: Purchase Order: Item Cost: Year Purchased: Cost New:	Delivery date: Warranty: Warranty Date Starts: Warranty Date End: Replacement Year: Replacement Cost:
Spare part availability: { } Yes { } No Service Manual availability: { } Yes { } No Operator Manual Availability: { } Yes { } No Number of Manuals:	

JOB REQUEST FORM

(User) Date: Location: Equipment name: Major complaint:
(Maintenance Department) Job category: □Pre-installation □Installation □Corrective maintenance Received / Request Date / Time: By : Model: Serial No:. Problem: Work done/required Material used/required
(Administrator) Instruction: Date / Signature
(Store/Procurement) Instruction received date: By: Date of procurement: By:
(Maintenance) Material received Date: By: Work result: Work completion date: By:
(User verification/witness) Received Date: Test confirmation signature:

Medical Equipment Inventory Check sheet

Equipment Inventory Check sheet																				
Department	Equipment Name	Manufacture	Model	SN	Country	Manufacturing year	Commission year	Manuals Mark(x) if available		Condition Mark (x) for applicable status					Frequency of usage				Temporary inventory number
								Service manual	Operation manual	Working	Minor repairer	Major repairer	Not working	Uncommissioned	Everyday	Few times per week	Few times per month	Not used	

Medical Equipment Acceptance Report

This is certifying that the following acquired medical equipment has been fully checked and inspected.

Purchase order NO.: Vendor:

ITEM	DESCRIPTION	MODEL	SERIAL NUMBER	MANUFACTURER
1				
2				
3				
4				
5				

	Yes	No		Yes	No		Yes	No
INSTALLATION COMPLETE	√		PART LIST			WARRANTY PPM SCHEDULE		
SERVICE MANUAL			ACCESSORIES COMPLETE	√		END USER TRAINING DONE		
OPERATOR'S MANUAL	√		WARRANTY CERTIFICATE			BIOMED TRAINING COMMITMENT		

TECHNICAL INSPECTION	CLINICAL INSPECTION
ACCEPTED ☐ ON HOLD ☐ REJECTED ☐ Remarks: _____ _____ Biomedical Eng. Manager Date	ACCEPTED ☐ ON HOLD ☐ REJECTED ☐ _____ _____ End User Dept. Head Date

Procurement plan

No.	Department	Equipment	Consumables/ Spare parts	Quantity	Unit cost (estimate)	Total cost (estimate)	Note

Service Report Form:

Date	DD	MM	YY	Location				
Instrument	ID Code		S/N	Cycle Counter	SRV	D	WC	H.G
Engineer	Name			Signature				

- Problem Statement:

- Work Done:

Work Pending: Recommendations:	Dept. Head Name: Dept. Head Signature:

Specification Form:

Item No.	QTY	Unit	Description
	01	EACH	Equipment Name
			1. Features
			1.1.
			2. Specifications
			2.1.
			3. Accessories & Consumables
			3.1.
			Standard Specification:
			1. Power plug type twist lock plug / Hospital grade .
			2. Operating manual (Original Copy) two copies each
			3. Service manual (Original Copy) two copies each
			4. Recommended spare part list
			5. 10 Years availability of spare part list in Sudan market including the list of companies to purchase them
			6. PPM schedule & PPM procedure with estimated time to complete PPM per equipment
			7. 2 Years warranty including labor & spare parts and all software and hardware upgrades provided that technical training course for one biomedical engineer at the manufacturer's facilities . Or 5 years warranty including labor and spare parts and all software and hardware upgrades without providing the technical training course.
			8. Continuous end user's training and satisfactory demonstration as required by the users .
			9. Include pre-installation , installation and commission of the equipment.
			10. The schedule of pre-installation, installation and commission works must be submitted to biomedical engineering section.
			11. Service contract cost for 5 years percentage from system price (%).
			12. After the warranty period cost yearly cost of the maintenance (labor & parts).
			Product Information:
			1. Model release date
			2. Accessories if any (to put machine/system into operation)
			3. Special features of the product (other than mentioned on list) must be clearly mentioned.
			4. Conform to CE mark, FDA & SFDA clearance.
			Important:
			1. Original brochures must accompany the offers.
			2. Full access to the service mode.
			3. Technical data sheet must be filled together with the offer. Failure to fill the technical data sheet will be rejected.
			4. Vendor must provide the latest product of the manufacturer.

Surplus Assets Report

From:

To: Assets Unit Manager

The following RC tagged asset/s is/are become surplus to my department for the following reasons:

Not in use ☐

Excess to our requirements ☐

Not working ☐

Damaged ☐

Please arrange to send back to RC and delete from our accountability.

ITEM#	RC Tag#	Description
1 2		

Replacement Required ☐ Replacement not required ☐

Justification :

_____

_____

_____

_____

Department Head Signature: _____

Date: _____

Available/Approved ☐ Not Available ☐ Need Technical Report ☐

Approved by: _____

Assets Unit Manager

Technical evaluation Form:

Date:

Required Item	Vendor NO.1	Vendor NO.2	End User Approval
	Vendor Name	Vendor Name	
1. Equipment Name	Not Acceptable	Not Acceptable	

Conclusion and Recommendation:

- Vendor 1.
- Vendor 2.

Biomedical representative

Training Form of Medical Equipment:

Date: _____

Equipment: _____ Model: _____

Presenter: _____ Deprt: _____

No.	Name	DEPT.	Position	Signature
1				
2				
3				
4				
5				
6				
7				
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9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				

Signed by:

_____

Presentor/Instructor