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Medical Devices Procurement Protocol

برتوكول الحصول على الأجهزة الطبية

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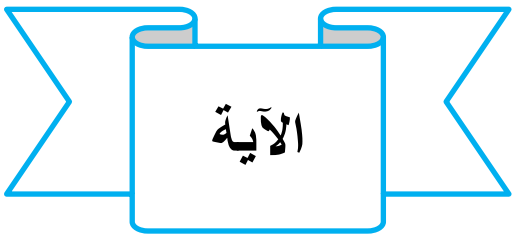

قال تعالى

﴿ بِسْمِ اللهِ الرَّحْمَنِ الرَّحِيمِ ﴾

﴿ اقْرَأْ بِاسْمِ رَبِّكَ الَّذِي خَلَقَ * خَلَقَ الْإِنْسَانَ مِنْ عَلَقٍ * اقْرَأْ وَرَبُّكَ الْأَكْرَمُ * الَّذِي عَلَّمَ بِالْقَلَمِ * عَلَّمَ الْإِنْسَانَ مَا لَمْ يَعْلَمْ ﴾

﴿ صَدَقَ الله العظيم﴾

سورة العلق الآية (1-5)

Dedication

I dedicate this research work to my parents who have been my constant source of inspiration.

To my family who supports me in everything.

To my subject teachers who never failed to teach and guide me.

To my friends who helped me to finish this project.

Last but not the least; I would like to thank my husband for giving me motivation and supporting me all time.

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Abstract

The appropriate management of medical equipment is vital for ensuring safe, effective, timely, efficient, and equitable healthcare.

Yet management of medical equipment is quickly becoming less effective by traditional methods because most healthcare delivery organizations must manage tens of thousands of medical devices. The management of these devices involves a wide array of activities including planning, procurement, inspection, inventory, testing, monitoring, maintenance, and de-commissioning so it became necessary to use modern computerized methods.

This research aims to design a protocol for medical devices procurement including acquisition & selection and computerization of selection process to preserve the internal budget of health care institution and to ensure that equipments used in patient care are safe, available, accurate, and affordable.

To achieve the objectives, Data was gathered by studying different mechanisms as well as gray literature and experts' opinion from various healthcare facilities in Khartoum state.

Also Questionnaire about medical equipment procurement was distributed and answered by biomedical engineers and were analyzed by SPSS program. And found that there is a lack in medical devices procurement policies and its application in many health care organizations.

Requirements for medical devices procurement was suggested and the selection process was programmed as software package using Delphi language then implemented in Ribat university hospital and obtained good results by providing high accuracy in calculations.

المستخلص

الإدارة المناسبة للمعدات الطبية أمر ضروري جداً لضمان توفير الرعاية الصحية الآمنة والفعالة وفي الوقت المناسب.
في الفترة الاخيرة اصبحت إدارة المعدات الطبية بالطرق التقليدية أقل فعالية و ذلك لأنه يجب على معظم إدارات تقديم الرعاية الصحية إدارة عدد كبير من الأجهزة الطبية وتشمل إدارة هذه الأجهزة مجموعة واسعة من الأنشطة بما في ذلك التخطيط والشراء والفحص والاختبار والرصد والصيانة وإلإحلال لذلك اصبح من الضروري استخدام الاساليب الحديثة المحوسبة.
يهدف هذا البحث إلى تصميم بروتوكول لشراء المعدات الطبية بما في ذلك التخطيط والاختيار بالاضافة الي حوسبة عملية الاختيار وذلك للحفاظ على الميزانية الداخلية لمؤسسة الرعاية الصحية وضمان أن المعدات المستخدمة في رعاية المرضى آمنة ومتوفرة ودقيقة، وبأسعار مناسبة.
لتحقيق أهداف البحث، تم جمع البيانات من عدة مصادرمثل المراجع و اراء الخبراء في المجال بالاضافة الى كتابة استبيان عن آلية شراء الأجهزة الطبية و وزع هذا الاستبيان على وزارة الصحة والصندوق القومي للإمدادات الطبية و مجموعة من المستشفيات العامة والخاصة داخل ولاية الخرطوم وتمت الإجابة على أسئلة الاستبيان عن طريق مهندسين طبيين و بعد تحليله عن طريق برنامج SPSS و وجد أن هناك ضعف في اليات الشراء و في تطبيقها في عدد كبير من منظمات الرعاية الصحية داخل ولاية الخرطوم.
تم اقتراح متطلبات لشراء الأجهزة الطبية كما تمت حوسبة عملية الاختيار باستخدام لغة Delphi ونُفذ البرنامج بمستشفى الرباط الجامعي وتم الحصول علي نتائج جيدة وعالية في الدقة.

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Abbreviations

Abbreviation	Core
CE	European Conformity
EEC	European Economic Community
EMD	Electronic Miscellaneous Document
EOI	Expressions Of Interest
EU	European Union
FDA	Food and Drugs Administration
FURLS	FDA Unified Registration and Listing System
HDO	Healthcare Delivery Organizations
HR	Human Resources
HTM	Health Technology Management
ICB	International Competitive Bidding
ICU	Intensive Care Unit
IDE	Investigational Device Exemption
ISO	International Organization for Standardization
LTA	Long-Term Agreements
MHRA	Medicine and Health Regulatory Agency
MTAA	Medical Technology Association of Australia
NCB	National Competitive Bidding
PMA	Premarket Approval
PO	Purchase Order
QC	Quality Control
QMS	Quality Management System
QRS	Quality System Regulation
RFQ	Request For Quotation
RFP	Request For Proposal
SPSS	Statistical Package for Social Science
SOW	scope Of work
TOR	terms Of reference
WHO	World Health Organization

Chapter One

Introduction

1.1 General View:

Medical devices are one of the most visible aspects of the modern world; it is impossible to avoid and uniquely compelling. People from all walks of life are eager to hear about new machines, new medicines, and new devices that will uncover hidden disease, treat previously untreatable ailments, and mend weary or broken organs.

Evidence for this high interest is everywhere; for example, new medical technology appears routinely on the covers of news magazines such as Time and Newsweek and in daily newspaper reports.

We know that modern medicine is built on steady progress in science, but it is just as heavily dependent on innovations in engineering. It is engineers who transfer scientific knowledge into useful products, devices, and methods; therefore, progress in biomedical engineering is arguably more central to our experience of modern medicine than are advances in science [1].

Effective management of this important resource is required to satisfy high quality patient care, clinical and financial governance, including minimizing risks of adverse events.

Medical equipment management has three essential aims: to ensure medical equipment in the clinical environment is appropriate to the needs of the clinical service, that it functions effectively and safely and that it represent value for money.

It is remit extend far beyond equipment repair and maintenance to include clinical governance and risk and asset management.

Successful acquisition of medical equipment involves clinical, technical and financial evaluations carried out by a wide range of qualified specialists, undertaken with regard to financial and corporative governance and in compliance with procurement regulations.

Life of the medical equipment stars with demonstrating a need for it, finding funding, writing specifications tendering and selecting the best option from those models on offer.

When an item is delivered, there should be acceptance procedures to check it works correctly and meet safety standards.

Users and biomedical engineers need to be trained and equipment has to be maintained and supported.

Procurement process including installation, training and maintenance must be documented by a rigor procuring contract.

1.2 Problem Statement

There is a serious lack of professional knowledge of appropriate acquisition and selection of medical equipment in many healthcare facilities represented in absence of a policy or mechanism for the acquisition or it’s not good enough to take into account

many considerations such as user specifications reliability, safety and after sales services.

1.3 Objectives

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

1.3.1 General Objectives

Increasing the quality and value of equipment services, saving organization money and Saving time and effort for the healthcare organization.

1.3.2 Specific Objectives:

- Determining requirements for medical devices procurement.
- Computerization of selection process.
- Implementation of the program.

1.4 Methodology:

Beside books and experts opinion data was gathered by studying different mechanisms of medical devices procurement from various healthcare organizations. Also Questionnaire about medical equipment procurement was distributed and answered by biomedical engineers and were analyzed by SPSS program to come up with a form for convenient design of the program. The mechanism was programmed as software using Delphi language and implemented.

1.5 Thesis Layout:

This dissertation comprises seven chapters; Chapter one introduces the problem and the objectives of the study. Chapter two describes the overview of medical device procurement process. The literature reviews are introduced in chapter three. Chapter four discusses the methodology and analysis. Chapter five involves Design and Implementation of the program. Chapter six includes the discussion. And finally Chapter seven is about conclusion and recommendations of this research.

Chapter Two

Theoretical Fundamentals

2.1 Terminology of medical devices:

2.1.1 Health technology:

The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life. It is used interchangeably with health-care technology [2].

2.1.2 Medical device:

An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose.
Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means [2].

2.1.3 Medical equipment:

Medical devices requiring calibration, maintenance, repair, user training, and decommissioning − activities usually managed by clinical engineers.
Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment.
Medical equipment excludes implantable, disposable or single-use medical devices [2].

2.2 Medical device classification:

The study of medical devices can be approached from at least four viewpoints. Techniques of biomedical measurement can be grouped according to the quantity that sensed, such as pressure, flow or temperature.
A second classification scheme uses the principle of transaction such as resistive, inductive or ultrasonic.
Measurement techniques can be studied separately for each organ system such as cardiovascular, pulmonary, nervous system. This approach isolates all important measurements for specialists who need to know only about specific area [3].
Finally medical devices can be classified into four categories according to their risks:

2.2.1 Class I devices:

Class I Medical Devices are simple in design and have little to no potential risk. Manufacturers are required to obtain an establishment license if they import or distribute through an entity that does not already hold a license.
The manufacturer is required to confirm that the facility has documented procedures for the distribution of records, as well as the handling of complaints and product recalls. Class I Medical Devices include tongue depressors, elastic bandages, hand held dental instruments and examination gloves [4].

2.2.2 Class II devices:

Class II Medical devices are more complicated in design and pose a minimal risk. A senior official of the manufacturer must attest to having objective evidence that the device meets safety and effectiveness requirements. Most medical devices fall into the Class II medical devices category such as X-ray machines, powered wheelchairs, infusion pump and surgical and acupuncture needles [4].

2.2.3 Class III devices:

Class III Medical Devices are sophisticated in design and have the strictest guidelines because they pose the greatest risk so the manufacturer must submit a summary of all studies on which it relies to ensure the device meets safety and effectiveness requirements. Class III medical devices support or sustain human lives therefore malfunction is absolutely unacceptable. Class III Medical Devices include implanted pacemakers, heart valves and implanted cerebral simulators.

2.3 Medical device management:

The appropriate management of medical equipment is vital for ensuring safe, effective, timely, efficient, and equitable healthcare, yet management of medical equipment is quickly becoming less effective by traditional methods.
Most healthcare delivery organizations (HDO) must manage tens of thousands of medical devices, the management of these devices involves a wide array of activities including planning, procurement, inspection, installation, commissioning maintenance, and de-commissioning. Many of these devices are becoming networked, but there are no common standards-based technologies for supporting these device management & maintenance activities [4].
As more equipment becomes connected to the enterprise network, it would be beneficial to equipment management activities to also be electronic and able to use these networking capabilities.
There are several potential benefits of this electronic approach to medical equipment management:

- Increases in patient safety by having safer, more reliable equipment available to clinicians when and where they need it.

- Reducing equipment failures through proactive maintenance.
- Managing the risk associated with networking medical devices.
- Tracking devices.
- Making sure devices are configured correctly.
- Evidence based maintenance planning could be fully realized with the automated, electronic reporting of maintenance information; this could allow devices to be scheduled for maintenance when they actually need it.
- Devices could also be more effectively used requiring fewer inventories [4].

2.4 Medical equipment life cycle:

The cycle of the medical equipment can be divided into 4 phases and 9 topics.

2.4.1 Planning phase:

Planning consists of Planning and Assessment of the needs in the healthcare facility appropriate to its environment, the equipment users and patients, and Budget & Financing in which the appropriate budgets are created and estimated for purchase.

2.4.2 Purchase phase:

This phase contains Assessment and Selection, covering how to decide which equipment meets the needs identified earlier.
Specifications are written and in Acquisition & Logistics.
A tender is written, a less complicated purchase is done or a donation is agreed upon.
The responsibilities and practicalities around logistics are prepared and executed. In Installation & Commissioning after the equipment has arrived in the healthcare facility and should be unpacked, installed, and commissioned.

2.4.3 Actual Lifetime phase:

The actual Lifetime of the medical equipment Starts with the training of users and maintainers in Skill Development & Training, the daily Operation & Safety for and by users, and Maintenance & Repair mostly done by the biomedical equipment professionals.

2.4.4 Decommissioning & disposal phase:

‘End of Life’ is about decommissioning & disposal of medical equipment.
Monitor & evaluate are constant throughout the life cycle. They contribute to keeping track of the equipment lifecycle, and create opportunities to review and improve processes and share successes and learning. Creating awareness with all participants, whether they are users, maintainers, administrators or politicians, is of great importance to improve systems and add to better biomedical and healthcare practices [4].

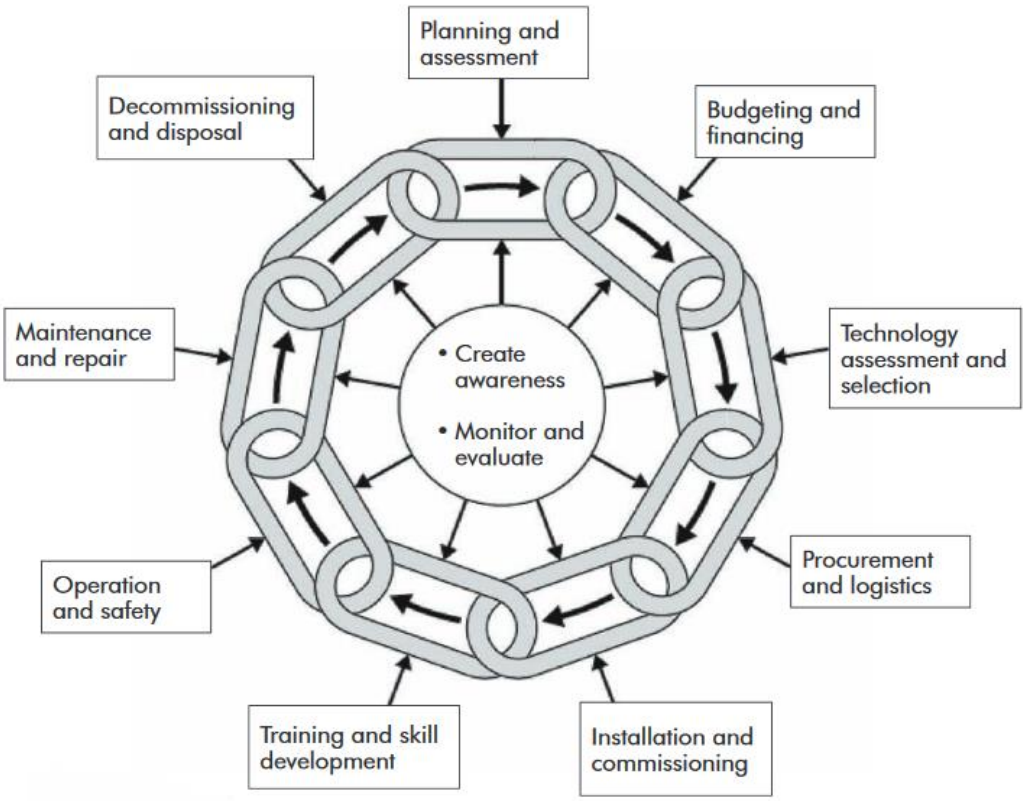

Figure (2.1): Flow chart of medical equipment life cycle [4].

2.5 Process for procurement of medical devices:

Procurement of healthcare technologies is often challenging given the wide choice of products and suppliers in the global market. Understanding of the needs at each level of the health system is critical and should be the first step.

Clear technical specifications and good procurement practices are necessary to guide sound procurement decisions. This is especially important to ensure that appropriate and safe equipment of good quality are placed in health facilities according to the needs.

Technical experts with specific knowledge in the selection and use of medical equipment including end-users should be involved in procurement processes for medical equipment.

The Process for procurement of medical device includes different phases illustrated in table 2.1:

Table (2.1): procurement of medical device phases

Phase	Activities
Planning phase	Needs assessment Procurement planning Product selection Product quantification and forecasting
Implementation phase	Product specification Tendering Vendor selection Tender evaluation Tender response
monitoring and evaluation phase	Monitor supplier performance Post market surveillance

2.6 Planning Phase:

All organizations, whether governmental, non-governmental or private, have limited resources that must be utilized in the most efficient means possible.
The importance of good advanced planning must never be underestimated as it provides critical information management requires allocating resources that will enable the organization to reach its objectives.
The procurement planning process includes several stages ranging from a preliminary needs assessment through key communication and decision-making stages to the actual development of a written plan.
The final stages include the selection and quantification of products.
Planning is an iterative process that requires continuous review and input from key stakeholders, good communication between parties and flexibility in approach [5].

2.6.1 Needs Assessment:

Needs assessment is a process for determining and addressing the gaps between the current situation or condition, and the desired one.
It is a strategic activity and a part of the planning process that aims to improve the current performance or to correct deficiencies.
A thorough needs assessment must be made at each level of national health system as the health facilities will vary within country, particularly in terms of human resource capacity, physical infrastructure, and client through-put.
Needs assessment takes into account the overall objectives of the institution, existing facilities and infrastructures, long-term plan of use, and human resources (HR) development prior to purchasing a medical device [6].

2.6.2 Procurement planning:

A national procurement and supply management plan contains information about what will be procured (commodities or services), when it needs to be procured by (delivery date), where it will be delivered to (location), who will be procuring (who does it and who else should be involved), and how the procurement will be processed (what method).
The plan helps to establish the timelines.

2.6.3 Product selection:

Product selection refers to the process by which preoperative departments, surgical service areas, and hospitals as a whole select, evaluate and ultimately procure the products they use and consume.
The following factors should be considered for product selection:

2.6.4 Appropriateness:

Supplies and equipment should be appropriate for the setting in which they will be used. Many issues should be considered such as: Local conditions, Compatibility and Acceptability items that are too technically sophisticated should be avoided, the latest model often requires more expertise to use and maintain, and complicated items tend to break down more frequently.
When thinking about procuring a particular item, it can be useful to talk to someone in a facility that has experience of using that model.
Reliability and durability need to be checked under local conditions.
Supplies and equipment should be compatible with existing equipment and appropriate for the level of service provided by your facility.

2.6.5 Quality:

Every device has a designed purpose. A device is clinically effective when it produces the effect intended by the manufacturer relative to the medical condition. For example, if a device is intended for pain relief, one expects the device to actually

relieve pain and would also expect the manufacturer to possess objective, scientific evidence, such as clinical test results, that the device does in fact relieve pain [7]

Medical devices must be of sufficiently high quality in terms of: Performance, Safety, Materials and design, labeling and packaging.
The quality of performance depends on how often an item will be used and how long you are expecting it to last.

2.6.6 Safety and performance standards:

All medical supplies and equipment should meet international, regional or national safety and performance standards.
The most important standards include:

- **European CE Marking for Medical Devices:**
  To sell medical devices in the European Union (EU), you must obtain or apply CE Marking for your product. CE Marking indicates a product's compliance with the applicable EU regulations and enables the commercialization of your products in 32 European countries. As a legal medical device manufacturer, you are responsible for maintaining regulatory compliance and securing CE marking for your product, regardless of whether you outsource any or all components of your manufacturing operation [8].

  CE is not a quality mark, but compliance with EU Directives requires you to meet specific standards of performance, quality, safety, and efficacy for your product type [8].

  The basic process follows these steps:

1. Determine which EU Directive applies to your device: Medical Devices Directive (93/42/EEC), In Vitro Diagnostic Devices Directive (98/79/EC) or Active Implantable Medical Devices Directive (90/385/EEC).
2. Determine the classification of your device.
3. Implement a Quality Management System, if applicable to your device. Most companies use ISO 13485 to meet the requirements.
4. Prepare a CE Marking Technical File or a Design Dossier.
5. Select and appoint a European Authorized Representative to act on your behalf within the EU if you have no physical location in Europe.
6. Have your QMS and Technical File/Design Dossier audited by a Notified Body, unless your device is Class I, is not sterile and has no measuring function.
7. Obtain CE marking and ISO 13485 certificates from your Notified Body.
8. Prepare a Declaration of Conformity which states that your device complies with the appropriate Directive [8].

- **FDA Marking for Medical Devices:**

  All companies planning to sell a medical device in the United States need to register their product with the US FDA. Most Class I devices can be self-registered but most Class II devices require a 510(k) submission. For Class III devices, a Pre-Market (PMA) submission is needed. The steps below provide a brief overview of how the PMA and the FDA 510(k) process work [9].

  The US FDA medical device approval process:

1. Determine the classification of your device by searching the FDA classification database.
2. Most Class I devices have to comply with the QSR (GMPs), except for Part 820. For Class II and III devices, implement Quality Management System (QMS) which meets the FDA Quality System Regulation (QSR) found in 21 CFR Part 820.
3. Innovative Class II, and all Class III, devices will likely require clinical studies. Get "Pre-Submission (Pre-Sub)" feedback from the FDA.
4. If clinical studies will be required, apply for an Investigational Device Exemption (IDE). Develop clinical trial protocol and conduct studies.
5. For Class II devices prepare and submit 510(k) Premarket Notification application and pay related fee. For Class III devices, prepare and submit Premarket Approval (PMA) application. Pay PMA submission fee.
6. For Class III devices, FDA conducts facility inspections of all major suppliers involved in the design and production of your device. All parties must be compliant with FDA QSR.
7. For Class II devices, the FDA issues 510(k) clearance letter and posts it online. For Class III devices, the FDA issues PMA approval letter and posts it online.
8. At this time, you must be in full compliance with QSRs. The FDA will not inspect Class I or II device manufacturers for compliance prior to device registration but does conduct random inspections and can issue a Form 483 for non-compliance.
9. If you have no local presence in the US, appoint an FDA US Agent representative as a local point of contact with the FDA.
10. List your device and register your company using FURLS system on the FDA website. Pay fees for Establishment Registration and Listing which must be renewed each year.
11. You are now able to sell your device in the US. Your company and device registration status will be listed on the FDA website. Your authorization does not expire as long as no changes are made to the device design, intended use [9].

2.6.7 Costs:

Better quality supplies and equipment are more expensive, but cheaper supplies and equipment are often of poor quality. Buying the cheapest items can be a false economy, because they may need repairing or replacing more frequently so it may be more cost-effective to spend more on a higher quality item that is more reliable and that lasts longer.
Packaging also adds to the cost of supplies and equipment, but it is usually worthwhile purchasing goods that are well packaged because poorly packaged goods are more likely to be damaged in transit
In addition to the purchase cost, other initial costs to consider include:

- Import tax and customs duty.
- Transportation and insurance.
- Installation.
- Staff training.

You also need to check that your budget will cover operational (running) costs throughout the lifespan of the equipment, including:

- Consumables and accessories – allow for continuity of these supplies
- Maintenance, Spare parts and servicing
- Kerosene, electricity or other fuel
- Safe waste disposal [10].

2.6.8 Source:

Another important factor is the source of supplies and equipment.
There are issues to consider related to:

- Manufacturers and suppliers
- Imported supplies
- Used supplies

The quality of manufacturing standards differs from country to country.
Only procure supplies and equipment from a licensed, reputable and reliable source.
Find out if the supplier will provide all the necessary documentation for customs clearance and decide whether you can deal with import procedures, transport, insurance and other arrangements [10].

2.6.9 Use and maintenance:

It is essential that the facility can use and maintain the procured supplies and equipment. There is no point in obtaining items if the staffs do not have the expertise or information to use them effectively or if the facility cannot access maintenance support and technical back up.
The facility should have the utilities needed to use an item of equipment.

2.6.10 Material:

Another important consideration is the material an item is made from. Instruments made from tungsten carbide last longer but are the most expensive; Instruments made from good quality stainless steel last longer than plastic instruments but are more expensive.
Make sure metal items that need to be cleaned and sterilized or disinfected regularly have a polymerized finish, polyester coating, epoxy coating or are made from good quality [10].

2.6.11 Disposable or reusable:

Some equipment, such as ventilators and anesthesia, have accessories that are available as disposable and as reusable products, and you may need to decide which type to procure. Both types have advantages and disadvantages in terms of convenience and cost. Disposables are more convenient than reusables however; using disposables costs more than reusables, because they need to be replaced more often.
When comparing costs you also need to include the cost of sterilizing reusable equipment.
If there is a national or local policy regarding the use of disposable or reusables it is usually easier and more practical to follow existing policy [10].

2.6.12 Consumables:

Consumables are other equipment items that are required to perform certain procedures.
These may be general items that can suit a variety of purposes e.g. gloves, lancets, alcohol swabs, specimen collection equipment, etc.
Special care should be taken to ensure these important commodities are included in procurement plan as stock-out of essential consumables will disrupt the services of the equipment and/or affect the safety of the end user.

2.6.13 Infrastructure and utilities:

The appropriateness of facility physical infrastructure must be reviewed prior to initiation of procurement.
Consideration must be given to the setting where equipment will be placed.

2.6.14 Quantification:

Quantification is the process by which requirements for equipment, consumables and durables are made. The quantification process requires significant preparation to ascertain the current scope and demand for products. A significant part of the quantification process is dedicated to the development and adjustment of forecasting models.

2.6.15 Forecasting:

Forecasting is a projection of the quantities of product required to meet demand for a future period of time.
Forecasts are most often made for a 1-2 year period.
Demand data from the field are essential to producing accurate forecasts.
The lack of available high quality demand data contributes greatly to low quality forecasts and resultant stock-outs and wastage of supplies.

2.7 Implementation Phase:

The implementation of the procurement process should be undertaken after consideration of the needs and it contains the following:

2.7.1 Product specifications:

Product specifications are detailed statements of the buyer's requirements covering both the technical and commercial attributes that the product must satisfy for buyer acceptance.
Specifications must be clearly written to ensure transparent procurement that represents the highest quality for the best price. There must be sufficient detail to award the contract to the best and most appropriate vendor. Specifications must be clear and concise, and must avoid marketing jargon.
Along with considerations of product selection, it is important to indicate the required quality of the manufacturing process.

2.7.2 Tendering:

Tender means an invitation to offer for an item/items or work. All Public Sector purchases/Contracts, over a certain value has to be publicly notified through Tender solicitation by public advertisement.
Tender can be classified based on the requirement category or Procurement Type. There are various types of Tenders. However, main Categories of the Tenders are listed below:

2.7.3 Open Tender:

Open tender is an arrangement where an advertisement in local newspapers or trade journals invites contractors to apply for tender documents. Open Tender is a transparent process which ensures that only the contractor with the best price and meeting all the technical requirements will win the tender.

2.7.4 Limited or Closed Tender /Selective Tender:

In Limited Tenders, only pre-qualified or known bidders are allowed to participate. Limited Tenders are not advertised in newspapers, as a result other bidder generally do not come to know that such tender is floated. The Lowest Bidder or L1 generally wins the contract.

2.7.5 Single Tender:

Single Tendering means sending the Tender to one particular party. Normally, it is either for an item where there is only one supplier or for an item where the purchaser has developed confidence in one supplier only and would just like to verify the current price, delivery etc. Single Tenders are also sent for items of proprietary nature.

2.7.6 Negotiated Tender:

Under Negotiated Tender method normally one contractor is approached and such tender mainly used for specialist work such as Robotic-surgeons , in such case there are limited number of contractor who do such work in the market. It is based on one-to-one discussion with contractors to negotiate the terms of contract.

2.7.7 International Competitive Bidding (ICB):

This method for procuring goods and services that requires notification to the international community. Bidders from eligible countries, as defined by the contracting agency or country, are given an equal opportunity to bid.

2.7.8 National Competitive Bidding (NCB):

In such tender type only Local companies can participate. International companies are not allowed to participate.

2.7.9 Request for Proposal (RFP):

In RFP a company is required to submit only the Technical proposal.

2.7.10 Request for Quote (RFQ):

It is the same as RFP but more specific, and with more details in each part. An RFQ (Request for Quote) is used when an organization has already decided on a particular type of product or service, and wishes to see competitive pricing from multiple vendors of that service.

2.7.11 Vendor sourcing and pre-selection:

Vendors (manufacturers, suppliers and distributors) should be identified via a fully transparent process.

Due to the wide range of some equipment, it is pertinent to pre-select suppliers.

In pre-selection, a limited number of suppliers or contractors that best meet the qualification criteria for the procurement concerned".

Regardless of whether vendor pre-selection is employed, information should be collected to ensure that the vendor is commercially viable and capable of supplying to the terms of the bid. Where possible, vendor details should be entered into a database for future reference.

Methods for sourcing vendors include:

- Communication with technically experienced organizations such as WHO or other relevant procurement agencies;

- Publication of a request for Expressions of Interest (EOI) on the website of an organization /government or in a newspaper;
- Invitation of specific vendors based upon market research (should be performed in conjunction with an open advertisement such as website or newspaper).

It is critical that vendors be sourced in an appropriate manner. An EOI is only appropriate where the products have been evaluated for performance (independently of the manufacturer) and are approved for sale and use in the country of intended use.
In cases where the manufacturer, as opposed to the manufacturer's distributor, is approached, it is important to ensure prices are provided according to local distributor's charges. Price transparency is important to ensure financial resources are sufficient to cover all procurement costs.
Commercial considerations of the vendor are important; the prior commercial track record of manufacturer/vendor/supplier must be examined to ensure its long term viability, capacity to deliver and provide post-sales support.
Some common example commercial specifications include: evidence of previous large transaction, ability to maintain supply of equipment at specified temperatures during transit, and prior experience with country of supply or equivalent setting [5].

2.7.12 Tender evaluation:

Clear directions on the bidding process must be provided in the solicitation documents and must be adhered to rigidly. Receipt of bids must be carried out in a transparent and consistent manner and must ensure equity for all bidders.
Tenders may be received by hardcopy and can be stored in electronic format.
Commercial and technical evaluations may be performed separately.
The tender evaluation committee should consist of a specialist evaluator for each of these parts i.e. a technical evaluation team and a commercial evaluation team, consisting each of at least two or more appropriately qualified members.
The technical and commercial parts of the tender can be evaluated concurrently at the discretion of the bid evaluation committee.
Quality and appropriateness for purpose should be the primary evaluation criteria.
The tender evaluation is separated into three stages:

- The tender response
- Preliminary examination of tenders
- Evaluation of substantially responsive tenders.

Tender response**:** Tenders must be opened at the time specified in the solicitation documents and all participating vendors must be permitted to be present. At the opening, bid tenders must fulfill the requirements set out in the solicitation documents. Minor corrections that do not affect the substance of the tender may be made at this time.
The procuring entity shall reject a tender at this stage if:

- Bidder is not qualified.

- Bidder does not accept required minor corrections.
- Bid is not fully responsive.
- Bid is abnormally low.
- Unfair competitive advantage or conflicts Of interest are found.

Successful bid responses are registered and will then pass to the next stage of bid evaluation.

Preliminary examination of tenders**:** This preliminary review of tenders examines eligibility, completeness, errors, legal validity, bid validity, bid security, plus substantial responsiveness to commercial and technical specifications.
A preliminary review may be made of the technical specifications. At this stage, a check is made to verify that required documentation is present to support the tender.
The quality and correctness of that documentation is further assessed in the next stage.
Evaluation of substantially responsive tenders: After initial qualification, each tender is closely reviewed and the technical, (quality and performance) and commercial characteristics of offered products are evaluated in greater depth.

When evaluating equipment, quality and appropriateness for use are primary criteria.
Price comparisons should be made after the technical review.
Evaluation criteria are based upon technical specifications and commercial requirements.
It is important to ensure evaluation criteria are measureable and objective where possible.
Measurable evaluation criteria are important "to identify the Vendor for award in a fair and objective and transparent manner to minimize the technical and commercial risk that the Vendor selected will not be able to perform satisfactorily.
A tender may be found non-responsive and therefore be disqualified at any stage of the evaluation process. Any reasons for disqualification should be made and incorporated into the final tender evaluation report.
The lowest evaluated responsive bidder must be established i.e. the post-qualified bidder with the lowest price that offers best value for money.
Domestic preference and prevailing import duties on goods may also be considered at the final stage of the decision process.
The commercial viability of the company and sustainability of the product / technology must be examined.
Consumables and support platforms should be available for the working life of the equipment.
The procurement entity, in conjunction with technical experts, must assess the likelihood of risks to sustainability such as changes to platform technology, discontinuation of future support, and financial stability of manufacturer / distributor.
The procuring entity must promptly notify each vendor of selection or rejection decisions.

2.7.13 Contracting:

The contractual process begins once a bid has been awarded.
It is important that both legal and technical experts are involved in the development of contracts for equipment.
The method of contract may vary and will depend on the nature of product and of the solicitation.
Types of contract that may be employed include:
Purchase Order (PO): POs are reserved for low value procurements.
Terms and conditions are set forth within the PO which constitutes a legally binding contract between vendor and buyer.
Any related documents must be clearly indicated and supplied with the PO.
Customized Contracts: Due to the complexity of medical devices, customized contracts that are individually worded (as opposed to a set of standardized provisions) are usually required.
Customized contracts required detailed written information/instructions that clearly define the obligations of both vendor and buyer.
Customized contracts usually contain the following information:
An overarching document containing specific contractual provisions agreed between vendor and buyer; o Relevant portions of the solicitation documents including specifications, terms of reference (TOR) or scope of work (SOW); The vendor's submission including best and final offer provided in response to the RFQ, ITB or RFP.

Systems Contract: Blanket Pos and Long-term Agreements (LTA)
These types of contract are used for products that may be required on a recurring basis or over an extended period of time.
The buyer enters a mutual arrangement with a supplier to provide goods or services with quantities to be determined at prescribed prices or pricing provisions for a specified period of time. Long-term purchase agreements are common practice to ensure a reliable source of supply goods and services at the lowest price.
Each element should be carefully considered and appropriate language included in the contract to ensure protection for both buyer and seller.
Failure to address common issues and establish a plan for unforeseen circumstances may lead to lengthy court proceedings and substantial financial loss.
Such contracts are designed to facilitate rapid processing of procurement requests and unit prices may be decreased due to the purchase of larger product volumes. These types of contract require continuous close monitoring.
Benefits of an LTA include protection against unreasonable increases in price for the same product, saves costly and time-consuming annual procurement processes.
Contracts should ensure a clause for rejection or refusal of goods that do not conform to the specifications, as stated.
Payment of goods should not been deemed as acceptance of goods.
Specific terms and conditions may also be stated in the contract such as shelf life, manufacturing standards, lot testing requirements.

Contracting for equipment: Purchasers should carefully evaluate acquisition contracts to identify minimum volume commitments, service requirements, training that is included, user support, warranty provisions and accessories pricing discounts.
Negotiation of these elements in the contract is required to guarantee that the best value and the lowest costs are obtained from the vendor.
Everything in the contract is negotiable.
The vendor must be contractually obligated to provide manufacturer-approved installation either through the manufacturer, by the vendor themselves or using an in-country agent (sub-contracted by the manufacturer). The vendor must ensure that required calibration and/or QC tools, where necessary, have been ordered and arrive in a timely manner.
Details of all installation requirements must be included in the contract [5].

2.7.14 Warranty:

Warranties are usually required for medical equipment.
A warranty requires the manufacturer (or vendor) to ensure manufacturing faults are rectified within a specified time period, usually 12 months. Warranties usually include provision for equipment repair that includes parts and labour and/or total replacement where necessary.
Warranties should not be expected to cover problems related to poor/incorrect installation if not performed by the vendor or vendor-specified agent, use or maintenance. The exact nature of the warranty should be clearly specified in the contract.

2.7.15 Training requirements:

Training requirements must be specified in the contract.
The vendor is obliged to train users in the calibration, operation, (basic preventive maintenance and repair) of particularly dedicated equipment.
Training is usually divided into pre-service and in-service (meaning on-going) training, in order to maintain an acceptable level of proficiency, it is crucial that staff be appropriately trained and refresher training provided. High quality training results in improved equipment operation and less frequent breakdown.

2.7.16 Maintenance:

All equipment must be must be regularly maintained with both preventive and corrective schedules, irrespective of the claims made by vendors.
In all circumstances, basic regular maintenance can prolong the lifetime of equipment.
Preventive and corrective maintenance could be specified in the contract.

2.8 Monitoring and evaluation phase:

A wide range of indicators may be monitored i.e. routinely tracked over time through either a specific system for monitoring or existing data sources. Effective monitoring allows for better evaluation of the effectiveness of procurement processes [5].

2.8.1 Evaluating supplier performance:

Evaluating the supplier is an integral component of the procurement cycle. It is necessary to collate information concerning each consignment, including if the goods must be delivered in acceptable condition, if orders are full and complete, if complaints are handled appropriately, and if responses to breakdowns dealt with efficiently.
Data should be collected continuously and for each consignment, preferably by the procuring entity.

2.8.2 Post market surveillance for medical devices:

Ensuring continuous product quality and compliance with minimum performance criteria is another necessary part of the procurement cycle.
An experienced end-user may often identify problems related to the medical equipment.
Daily quality assurance measures will assist the user to obtain information about potential quality problems [5].

Chapter Three

Background studies

Corinna Sorenson and Panos Kanavos in (2011) discussed the procurement of select medical devices across five countries (England, France, Germany, Italy, and Spain) based on a review of published and grey literature and policy documents, as well as expert interviews. All countries have introduced various regulatory or policy measures that implicitly or explicitly influences device procurement, from lists of devices for purchase to changes in financing mechanisms. There has also been movement toward more centralized procurement with the introduction of purchasing groups or consortiums, notably in England, France, Germany, and Italy. While a number of stakeholder groups are involved in purchasing activities, a greater, more formalized role for physicians and governments is needed to ensure that technologies procured best meet patient needs and align with national health care priorities and other sectoral objectives. A general theme across all national procurement systems was a focus on cost-containment, but like other areas of technology policy (e.g., coverage), basing purchasing decisions on a broader range of criteria, such as quality and health outcomes, might better allow governments to achieve value for money and support patient access to beneficial innovations [11].

Nyassi et al 2013 explained that the acquisition of health technology management (HTM) is very important for health care, as it will reduce the number of major problems associated with health care technology, they said it should be introducing the HTM concept to as many stakeholders as possible within the national healthcare systems, and especially to the healthcare executives, policy makers and regional hospital managers administrators, this will in a long way alleviate major sticking problems especially associated within the initial phase of the HTM cycle, Acquisition of healthcare technologies including donations. It has led the establishment of biomedical engineering department and an HTM system has brought major solutions to inadequate maintenance capabilities, prolonged downtimes of equipment and the high maintenance costs that existed through existing service contracts [12].

Lesley Fallon in (2014) developed a policy for Medical Devices Procurement Procedure in (Newcastle Upon Tyne Hospitals NHS Foundation Trust) to provide guidance to all staff with responsibility for the purchase of medical devices as part of their work and for information to help all Trust staff to understand the processes involved when a new or replacement medical device is required. She established this policy to make all Trust staff aware of the procedures required to ensure that medical devices are procured in accordance with Trust Standing Financial Instructions, Public Contract Regulations and that goods and services are procured in a way that ensures value for money on a whole-life basis, not only generating benefits to the organization but also to society and the economy, whilst minimizing damage to the environment [13].

The Medical Technology Association of Australia (MTAA) in (2015) has developed a paper to propose reforms to the procurement of medical products and medical technologies in the public health system. MTAA member companies supply most of the products used by public hospitals and clinics.

The suppliers observe many instances where unnecessary costs are incurred by the customers as a result of inefficient and duplicative processes, or as a result of a shift in the equity balance between customer and supplier.

This position paper proposes several areas for reform. These are:

•National alignment of processes for public procurement of medical technology through the use of standardized terms and conditions and removal of duplicative requirements.

•Improved governance arrangements for public procurement for medical technology to ensure the maintenance of discipline and transparency in the procurement process.

•Mechanisms to achieve best practice in public procurement for medical technology.

•Support for skills development of health procurement officials. MTAA members have seen previous efforts at reform develop strong frameworks which are then not implemented. MTAA seeks to work with the States and their purchasing units to address the issues identified by suppliers. Simplification and standardization of the procurement of medical products and technologies will help to address the increasing pressure on health budgets [14].

Chapter Four

Methodology and Results

4.1 Methodology:

This section includes a description and justification of the methods used in this study. The research went through four stages: the first stage was collecting the data needed for designing the program, the second stage was analyzing the data to come out with the form of proper mechanism for acquisition of medical equipment, the third stage was programming the mechanism as software and the last stage was implementing this program.

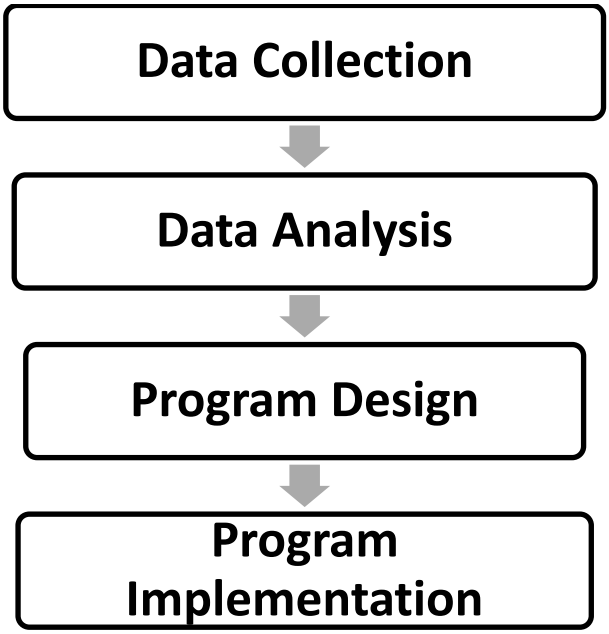

Figure (4.1): Study methodology Flow chart

4.1.1. Data Collection:

Data were collected from various sources such as former researches and books with respect to supply and installation contracts and experts' opinion.
A questionnaire about procurement of medical equipment was done and distributed to Federal Ministry of Health, National Medical Supplies Fund and thirty eight hospitals among Khartoum state and it was answered by a biomedical engineer from every healthcare institution.

4.1.2 Data Analysis:

Questionnaires were answered by biomedical engineers and were analyzed by SPSS program which obtain a number of results with the aid of statistical analysis.

4.1.3 Program Design:

The software has two parts the first one is for medical device data entry by bidders; it was programmed using Delphi language and web base technique to facilitate accessibility , the second part is for calculations and selection; it was programmed by Delphi language and the data base was created by MYSQL manager.

4.1.4 Program Implementation:

The software was implemented in Ribat University Hospital on a tender of seven medical equipment for intensive care unit, five medical equipment companies participated in the tender and results were discussed.

4.2 Questionnaire analysis results:

The questionnaire was distributed to the Federal Ministries of Health, National Medical Supplies Fund and thirty eight hospitals in different parts of Khartoum state and it was found that:

- Policy Presence:

Table (4.1): The percentage of healthcare institutions which have medical devices procurement policy.

	Frequency	Percent
Yes	38	95.0
No	2	5.0
Total	40	100.0

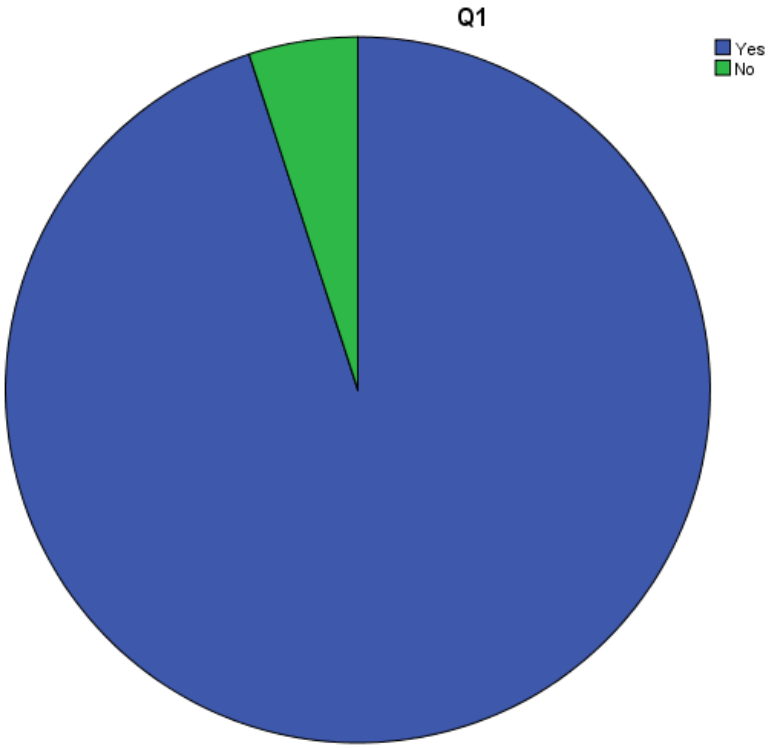

Figure (4.2): The percentage of healthcare institutions which have medical devices procurement policy.

It is found that about 95% of healthcare institutions have policies that are followed for the procurement of medical devices while 5% haven't as shown in figure (4.2).

- Team Existence:

Table (4.2): The percentage of the parties who perform the procurement operation.

	Frequency	Percent
Individual	**6**	**15.0**
Team	**34**	**85.0**
Total	**40**	**100.0**

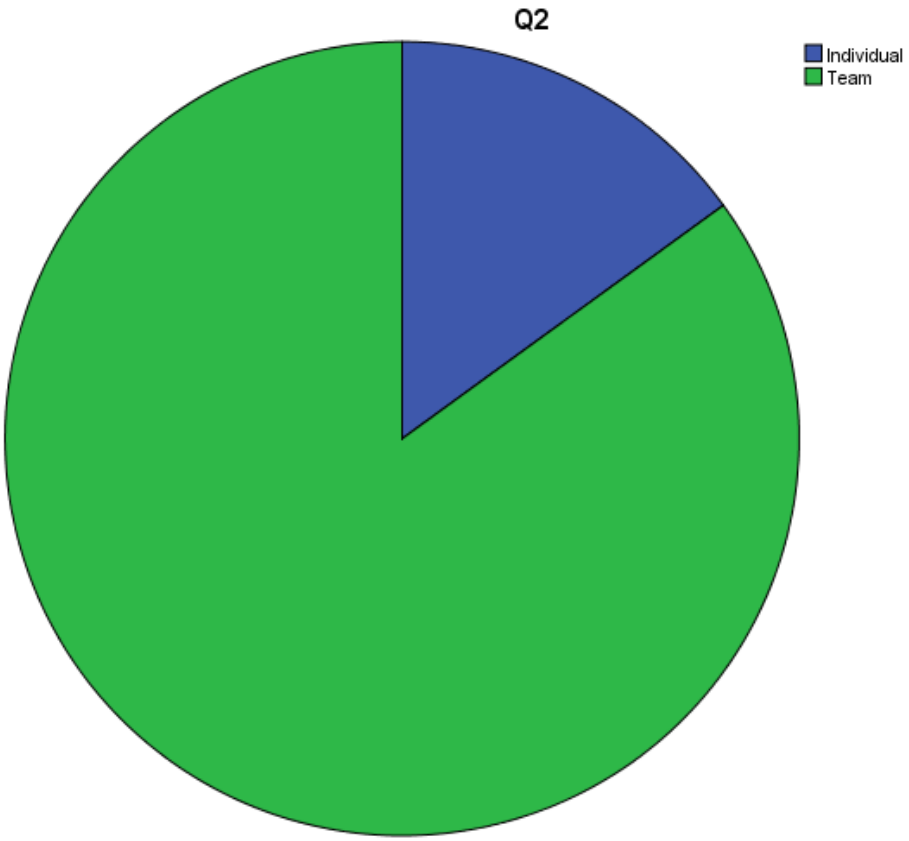

Figure (4.3): The percentage of the parties who perform the procurement operation.

It is found that the procurement of medical devices is done by a team in 85% and by individuals in 15 % of the healthcare institutions.

- Biomedical Engineer Presence:

Table (4.3): The percentage of teams which include biomedical engineer.

	Frequency	Percent
Yes	33	97.1
No	1	2.9
Total	34	100.0

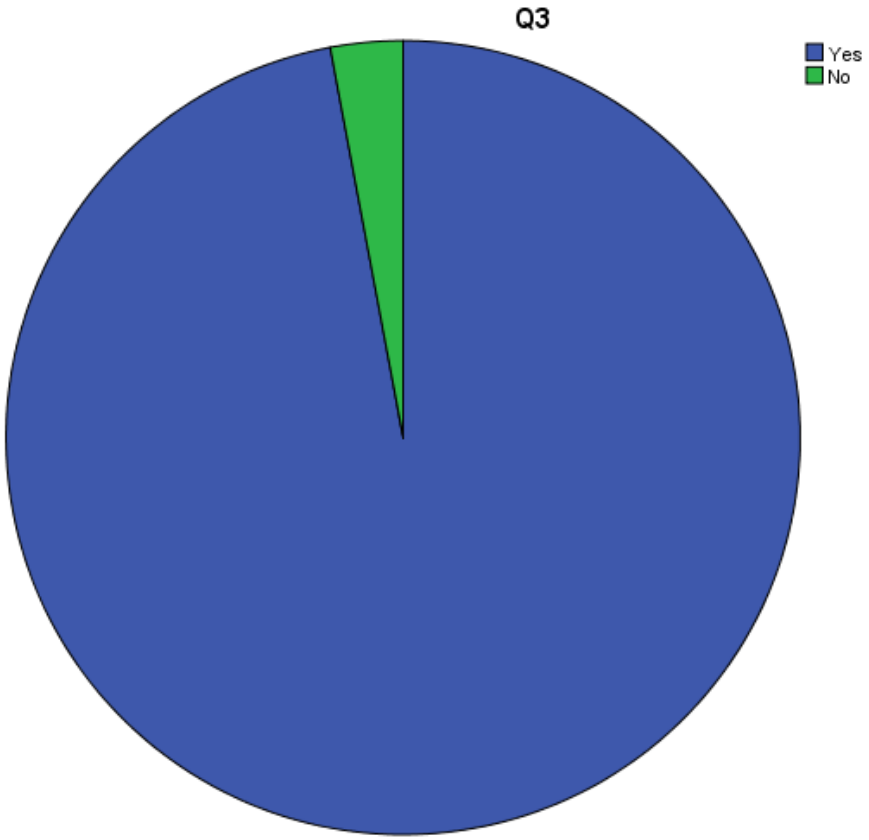

Figure (4.4): The percentage of teams which include biomedical engineer.

When medical devices procurement is done by a team, a biomedical engineer is included in the team in 97.1% of healthcare institutions and excluded in 2.9%.

- Supplier Type:

Table (4.4): The percentage of providers from which the medical equipment are purchased.

	Frequency	Percent
Agent	12	30.0
Distributer	6	15.0
Others	3	7.5
Agent & Distributer	19	47.5
Total	40	100.0

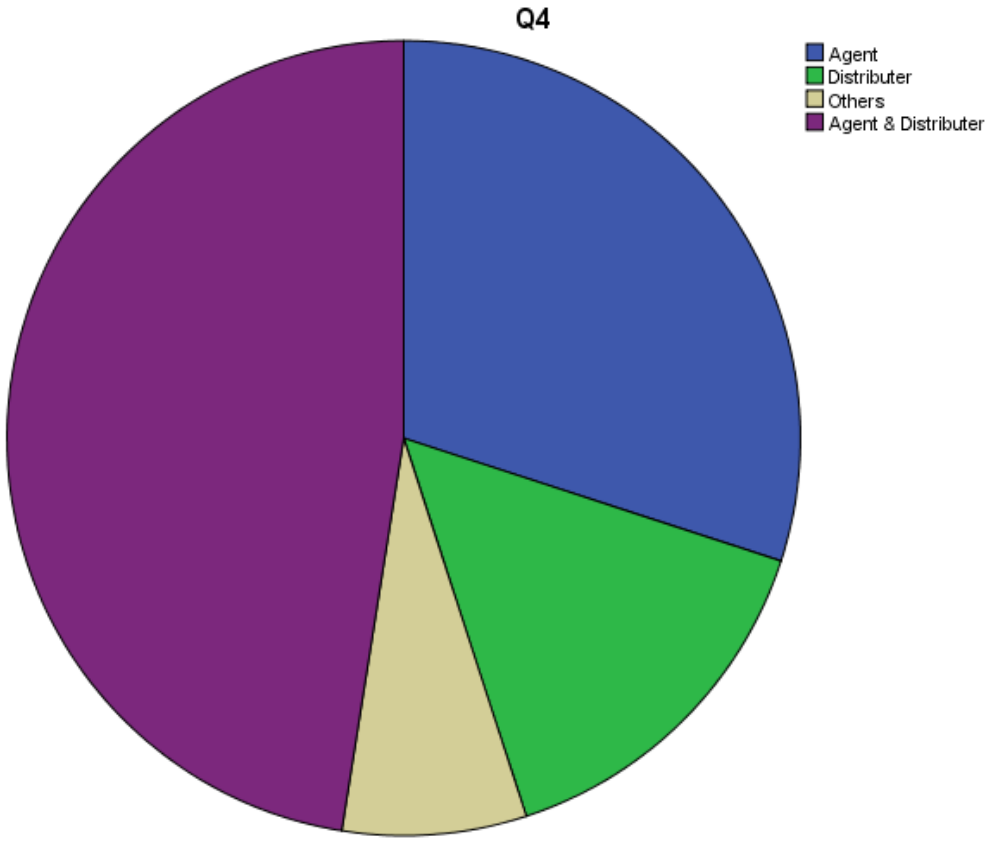

Figure (4.5): The percentage of providers from which the medical equipment are purchased.

About 47.5% of the healthcare institutions prefer to purchase from Agent Company and if there is no agent could buy from Distributer Company while 30% insist to Purchase from agent, and 15% purchase from distributer while 7.5% have other sources like National Medical Supplies Fund and Manufacturer plant as shown in figure (4.5).

- Forecasting Plan:

Table (4.5): The percentage of healthcare institutions that have forecasting plan.

	Frequency	Percent
Yes	9	22.5
No	31	77.5
Total	40	100.0

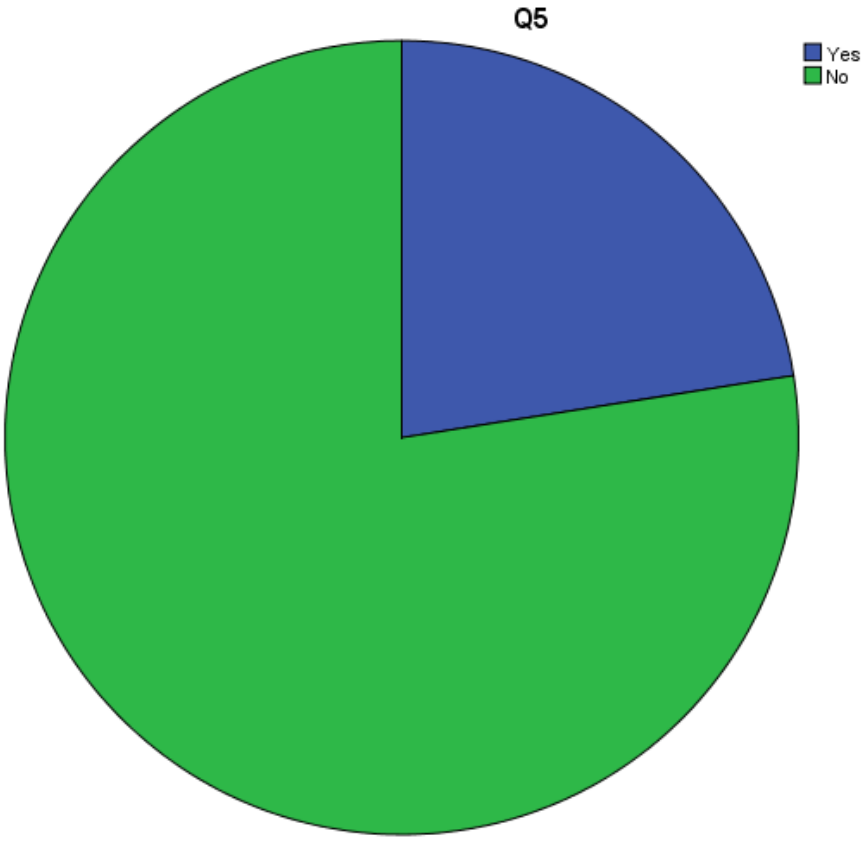

Figure (4.6): The percentage of healthcare institutions that have forecasting plan.

About 22.5% of the healthcare institutions have forecasting plan while 77.5don't have as illustrated in figure (4.6).

- Procurement Method:

Table (4.6): The percentage of the methods used for medical devices procurement.

	Frequency	Percent
Selective	24	60.0
Open	16	40.0
Total	40	100.0

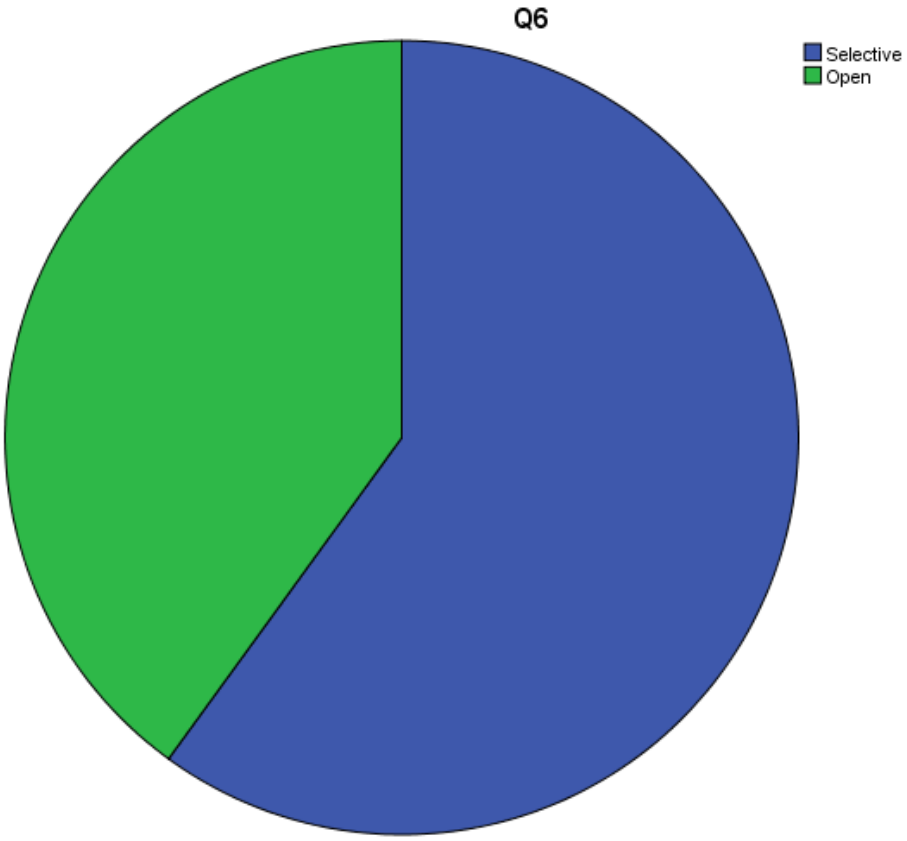

Figure (4.7): The percentage of the methods used for medical devices procurement.

The method used for medical devices procurement in 60 % of the healthcare institutions is selective bidders, while 40% open bidders.

- Approval Certification consideration:

Table (4.7): The percentage of the healthcare institutions that consider Approval certification an important part of purchase operation.

	Frequency	Percent
Yes	26	65.0
No	14	35.0
Total	40	100.0

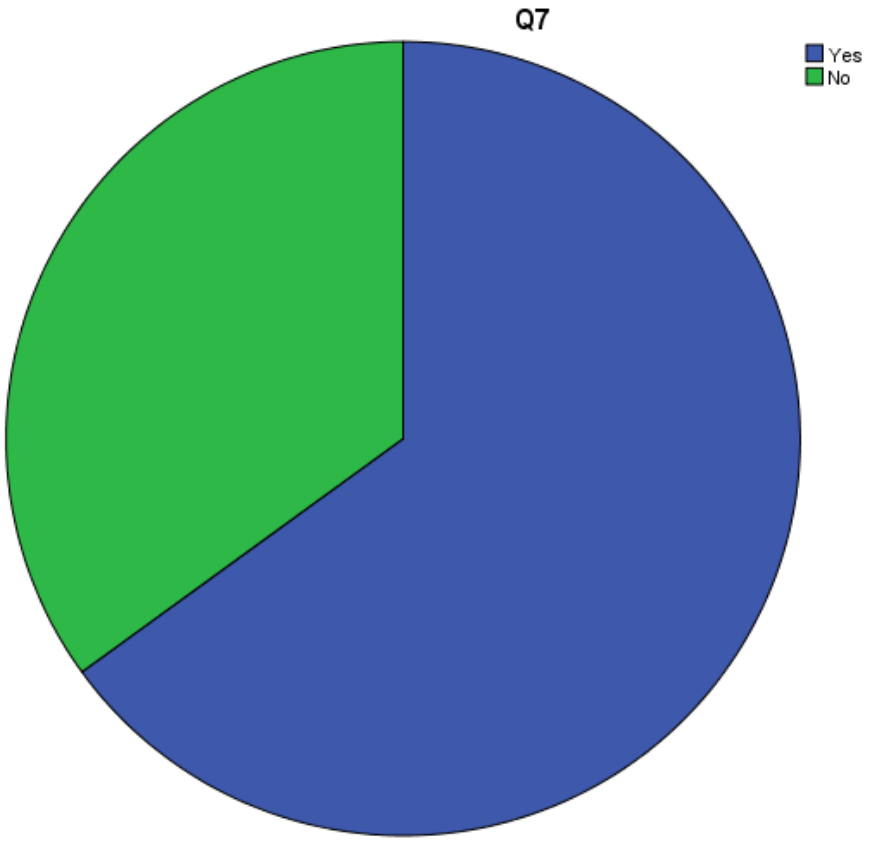

Figure (4.8): The percentage of the healthcare institutions that consider Approval certification an important part of purchase operation.

The Approval certification is considered as an important part of purchase operation in 65% while it is not in 35% of the healthcare institutions.

- Accredited Approval Certification:

Table (4.8): The percentage of accepted Approval certifications.

	Frequency	Percent
Specific	23	88.5
Any	3	11.5
Total	26	100.0

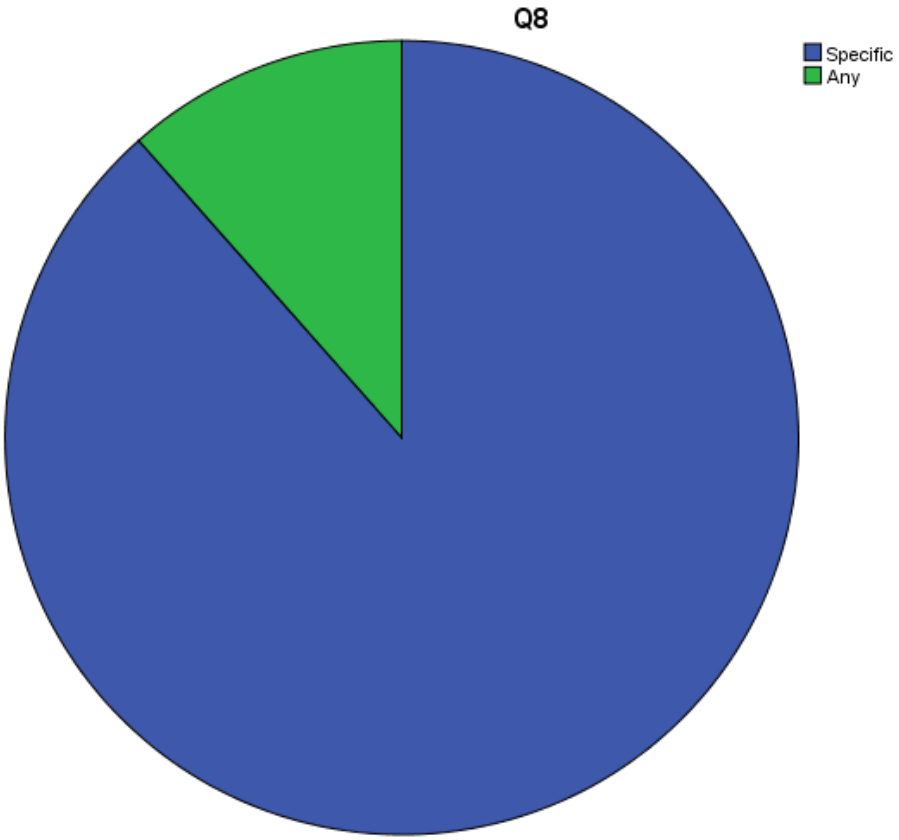

Figure (4.9): The percentage of accepted Approval certifications.

Specific certifications like (CE, FDA, ISO and TUV) are accepted in 88.5% of the healthcare institutions while any certification is accredited in 11.5% of them.

- Weights of Selection:

Table (4.9): Percentage of the weights of selection criteria.

	Frequency	Percent
20%Tech-80%Fin	2	5.0
30%Tech-70%Fin	1	2.5
40%Tech-60%Fin	2	5.0
50%Tech-50%Fin	2	5.0
70%Tech-30%Fin	5	12.5
80%Tech-20%Fin	2	5.0
Not Fixed	26	65.0
Total	40	100.0

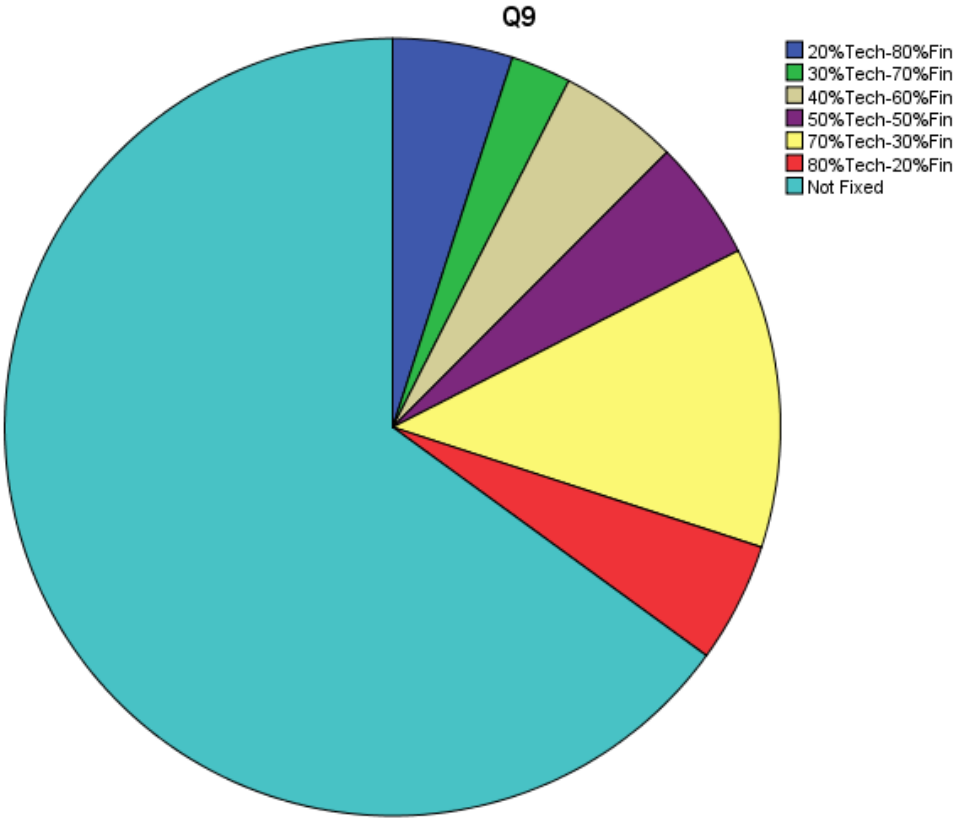

Figure (4.10): Percentage of the weights of selection criteria.

The weight of selection criteria had wide variations as illustrated in figure (4.10).

- Selection Method:

Table (4.10): The percentage of the method used for offers sorting and selection process.

	Frequency	Percent
Manual	24	60.0
Automated	4	10.0
Semi-automated	12	30.0
Total	40	100.0

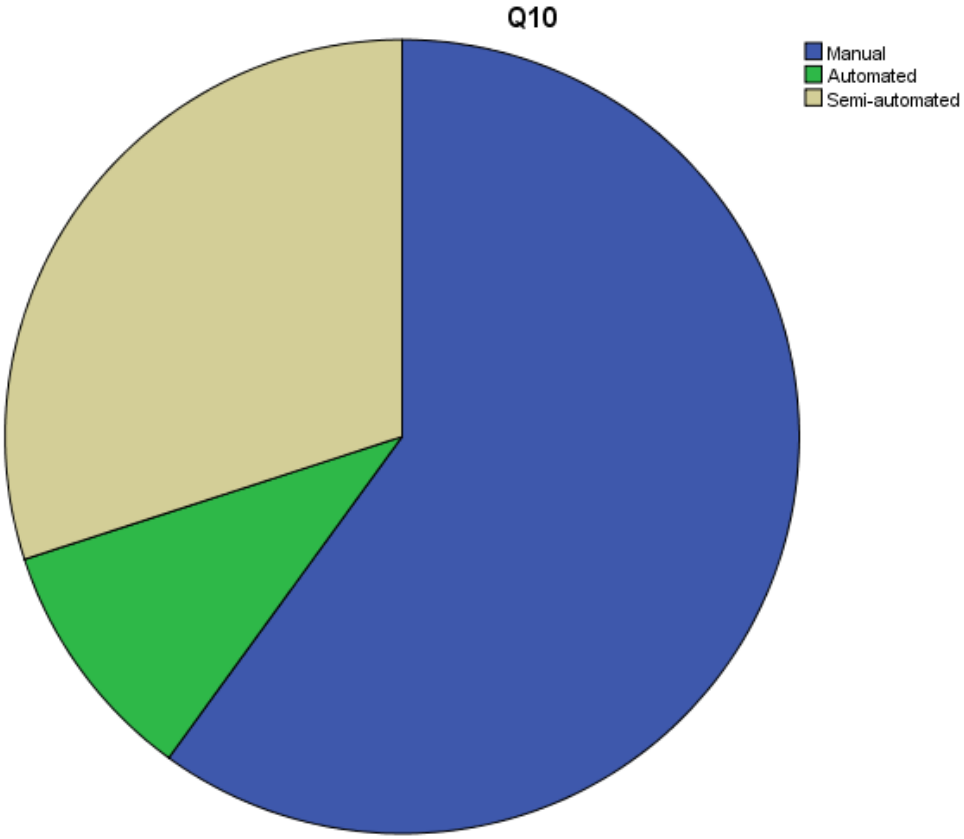

Figure (4.11): The percentage of the method used for offers sorting and selection process.

The method used for offers sorting and selection process is manual in 60% automated in 10% and semi-automated in 30% of the healthcare institutions.

- Programming Language:

Table (4.11): The percentages of the hospitals that use excel Microsoft package.

	Frequency	Percent
Excel	**16**	**100.0**

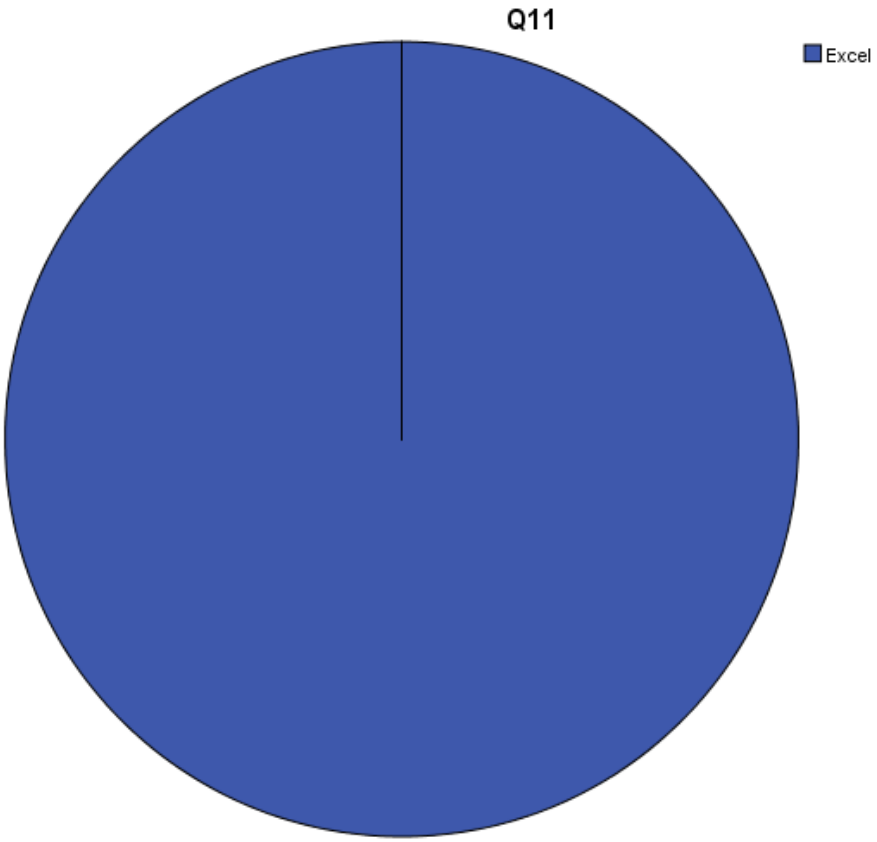

Figure (4.12): The percentages of the hospitals that use excel Microsoft package.

When the selection process is automated and semi-automated, excel Microsoft package is used in 100% of the healthcare institutions.

- Procurement Contracting:

Table (4.12): The percentage of the healthcare institutions which purchase medical equipment using contract.

	Frequency	Percent
Yes	39	97.5
No	1	2.5
Total	40	100.0

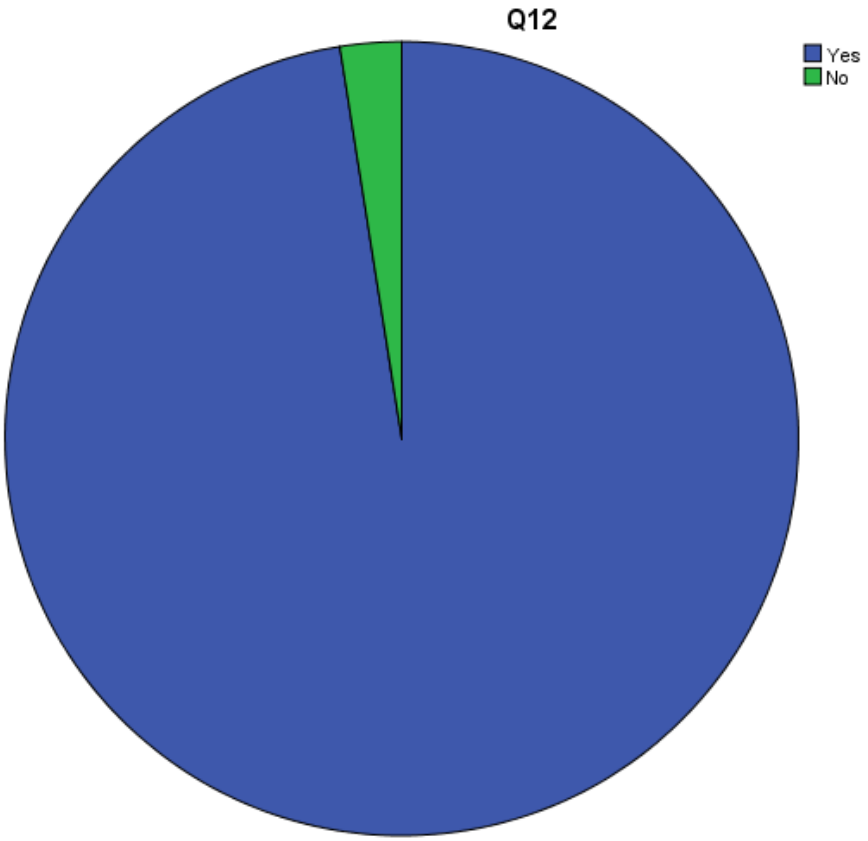

Figure (4.13): The percentage of the healthcare institutions which purchase medical equipment using contract.

Purchase of medical devices is done by a contract 97.5% of the healthcare institutions and without contract in 2.5 of them.

- Contract Terms:

Table (4.13): The percentage of points included in the contract.

	Frequency	Percent
Warranty	1	2.6
Training	1	2.6
Provision of Spare parts	1	2.6
Warranty & Training	3	7.7
All	33	84.6
Total	39	100.0

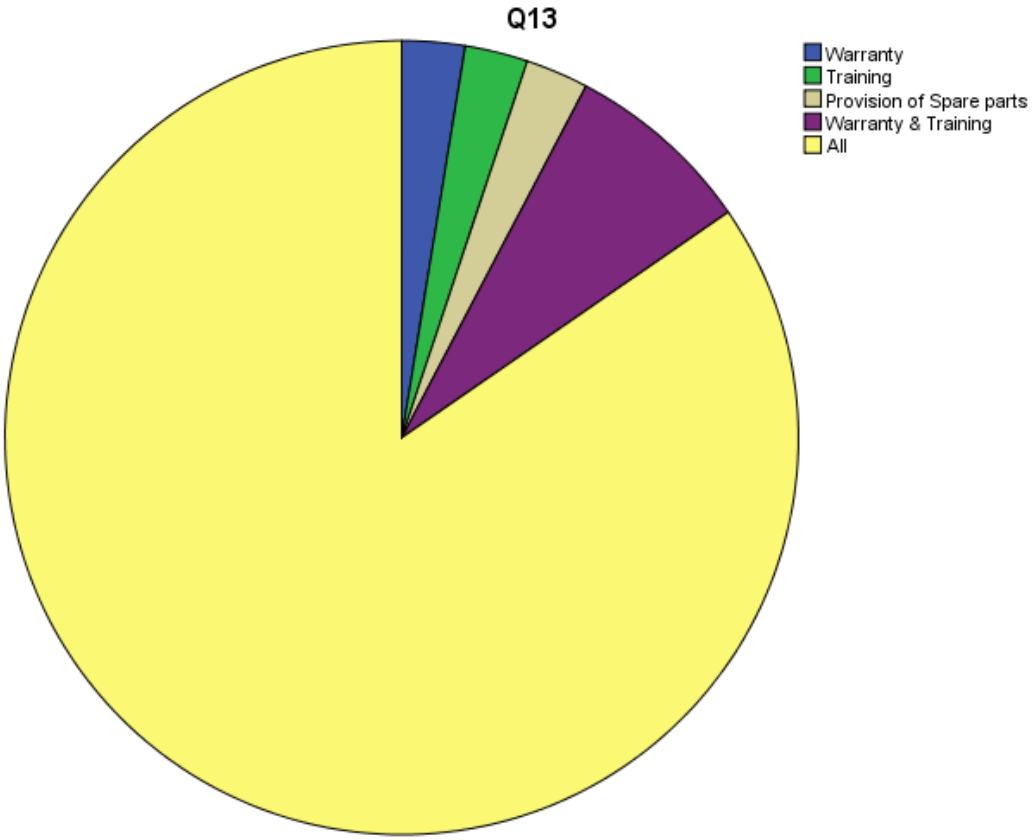

Figure (4.14): The percentage of points included in the contract.

The contract for medical devices purchase includes the warranty, training and provision of spare parts and technical support after warranty in 84.6% of healthcare organizations as shown in figure (4.14).

- Special Maintenance Tools:

Table (4.14): The percentages of the healthcare institutions which purchases special maintenance tools.

	Frequency	Percent
Yes	15	37.5
No	25	62.5
Total	40	100.0

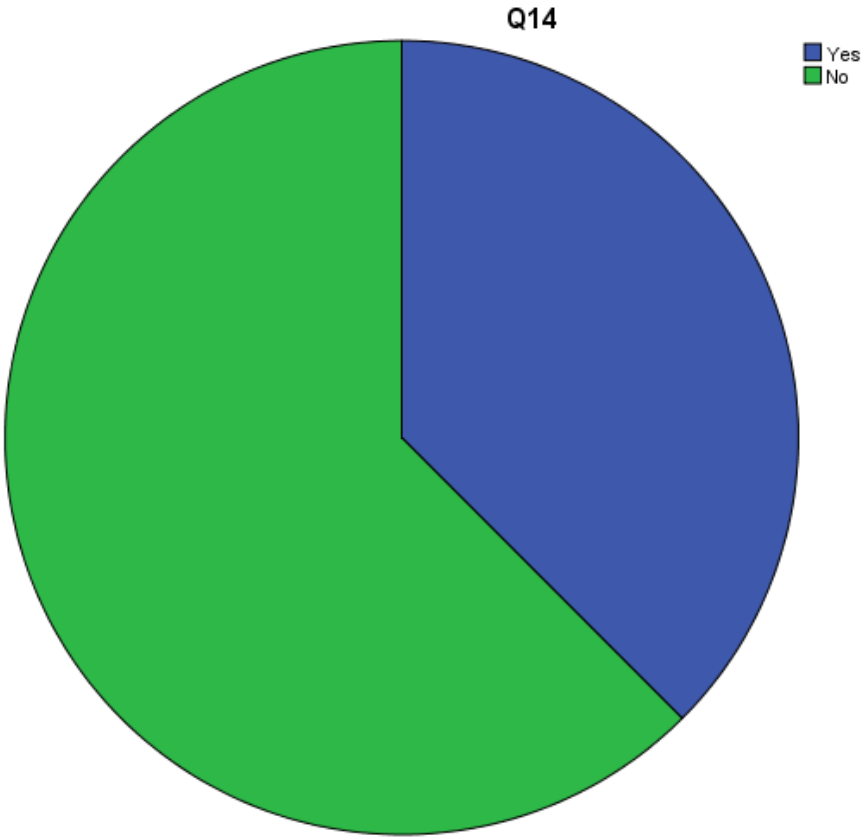

Figure (4.15): The percentages of the healthcare institutions which purchases special maintenance tools.

About 37.5% of the healthcare institutions purchases special maintenance tools with the medical equipment while 62.5% don't.

- Calibration and Quality Control Tools:

Table (4.15): The percentages of the healthcare institutions which purchases calibration and quality control tools.

	Frequency	Percent
Yes	9	22.5
No	31	77.5
Total	40	100.0

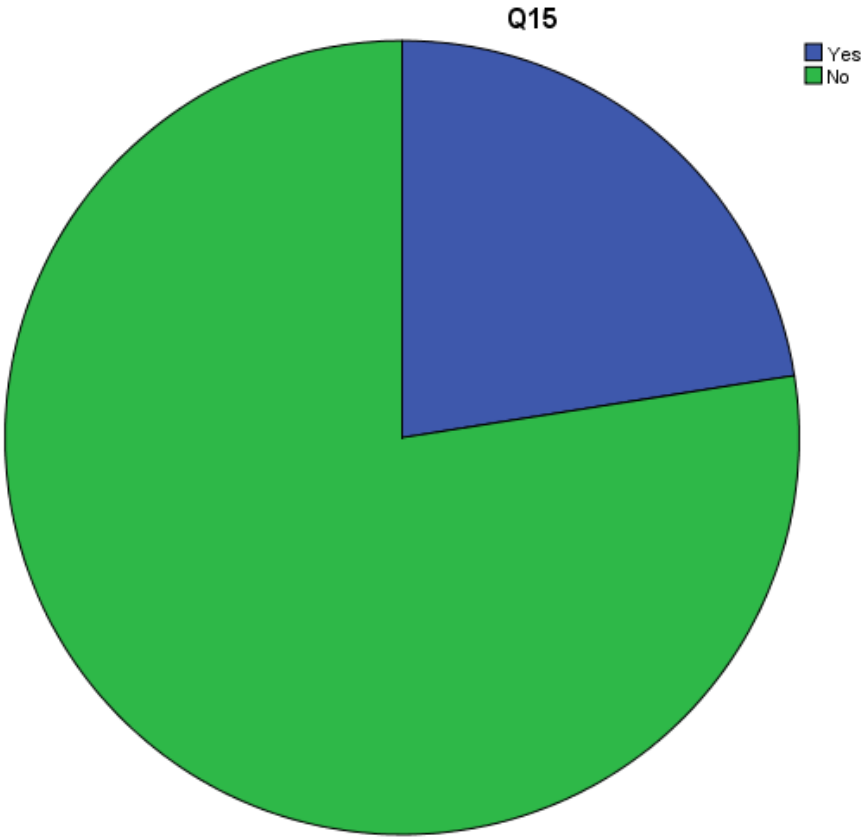

Figure (4.16): The percentages of the healthcare institutions which purchases calibration and quality control tools.

About 22.5% of the healthcare institutions purchase calibration and quality control tools with the medical equipment while 77.5% don't.

Chapter Five

Design and Implementation

5.1. Program structure:

The medical devices procurement program could be divided into three parts: data base, main body and user interface as illustrated in figure (5.1).

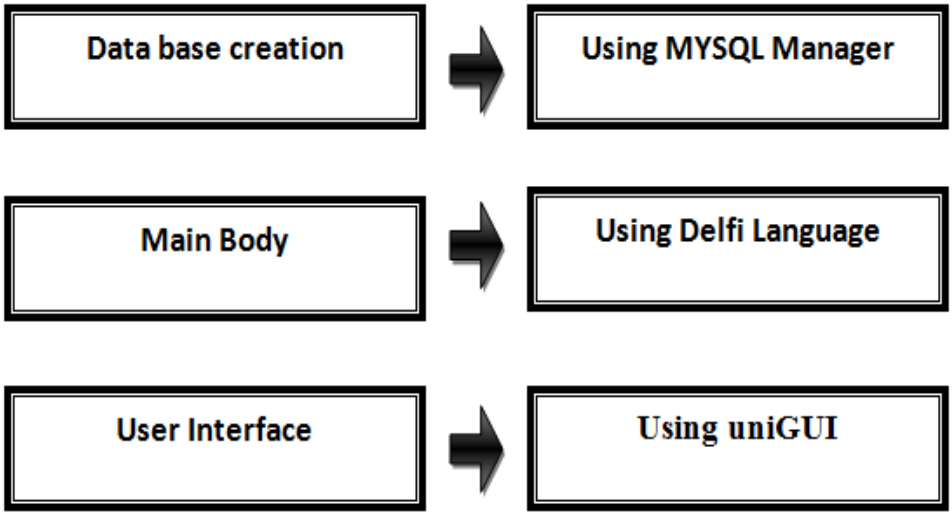

Figure5.1: Prime Parts of the Program.

5.1.1 Database:

The data base contains 3 tables and 40 fields for medical device related data such as medical device model and manufacturer.
It was created using MY SQL manager2005 .MySQL is an open source relational database management system. It is based on the structure query language (SQL), which is used for adding, removing, and modifying information in the database. Standard SQL commands, such as ADD, DROP, INSERT, and UPDATE can be used with MySQL.
MySQL can be used for a variety of applications, but is most commonly found on Web servers.

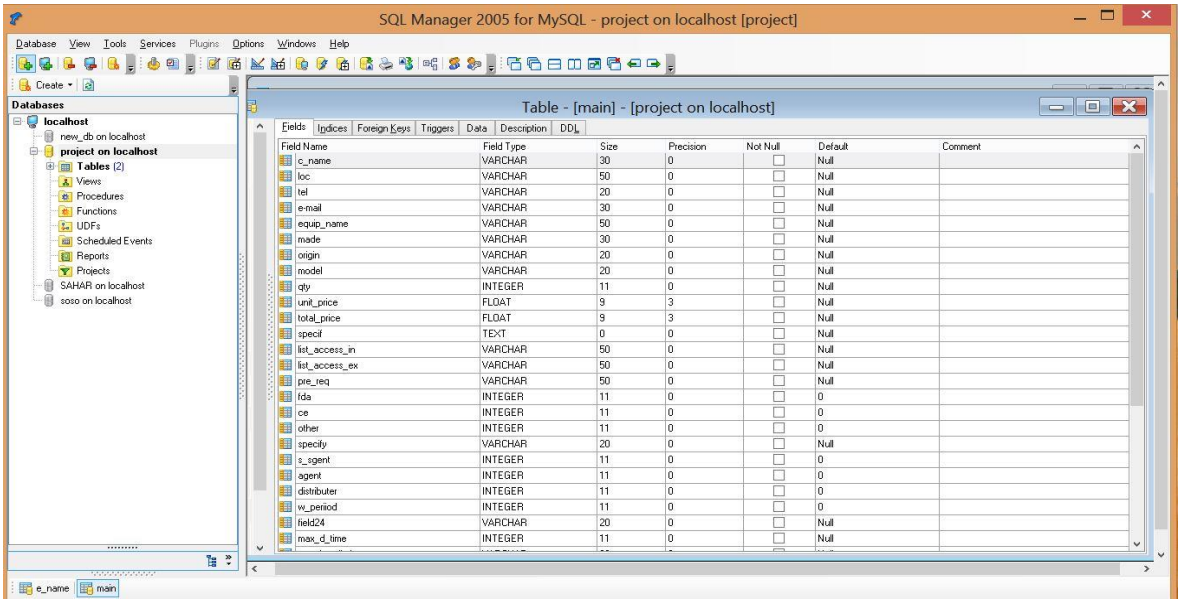

Figure5.2: program data base

5.1.2 Main Body

This part of the program is responsible for calculating predefined percentages for selection factors and calculating the final result for every medical device in the tender in order to determine the best offer. It was programmed by Delphi language. Delphi is both an object oriented programming language and an Integrated Development Environment It originated from the Pascal language, it is the choice for developers wanting the power, readability and flexibility of the Modern Object Pascal language, coupled with native compilers and component libraries for fast single source code development.

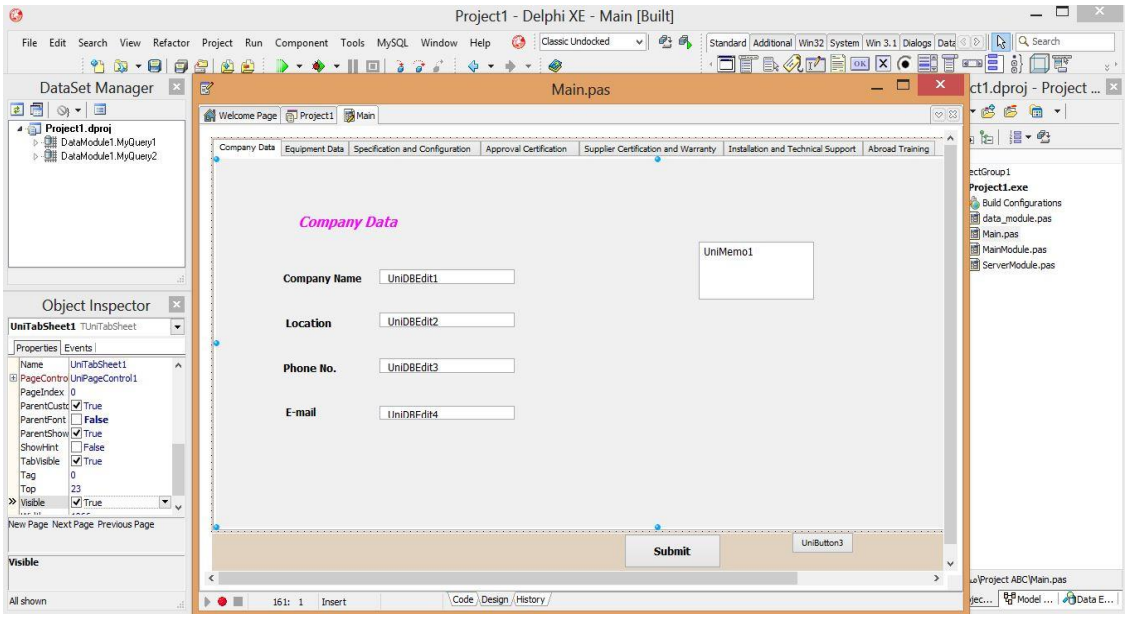

Figure5.3: Main body of the Program.

5.1.3 User Interface:

It was designed using uniGUI which is a Web Application Framework for Delphi. C++ Builder development is also supported for RAD Studio owners. uniGUI features a rich set of visual controls for developing stateful Web applications.. uniGUI Web applications can easily be run and debugged directly in Delphi IDE which makes development process very easy and straightforward. uniGUI allows developer to focus on application business logic rather than working on web application development details such as working directly with HTML, JavaScript, XML Templates, and other web technologies.

The user interface consists of seven pages for entering information related to medical devices:

- First page is for company data.

Figure5.4: Company data.

- Second page contains medical equipment/ device data.

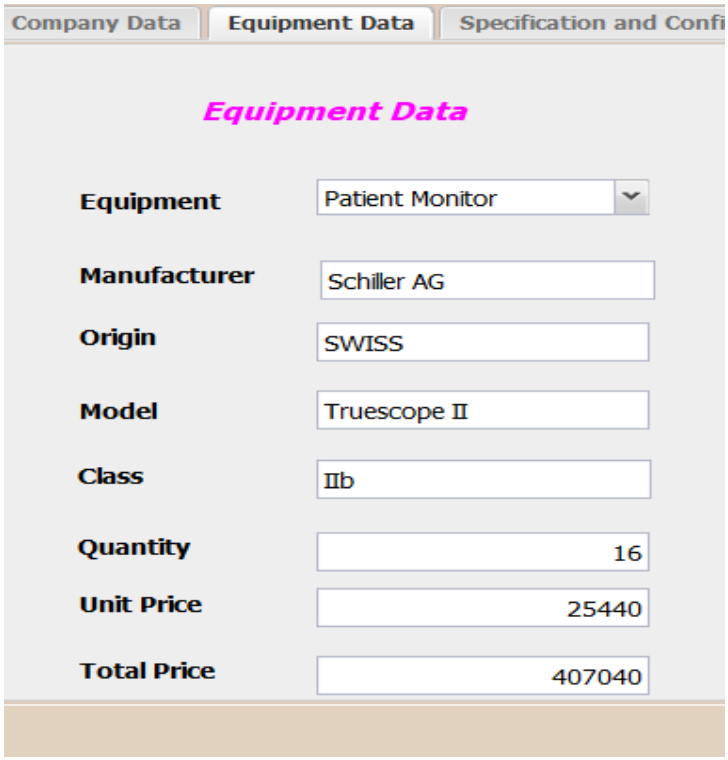

Figure5.5: Medical equipment/ device data.

- The third page include specifications and configurations of the medical device

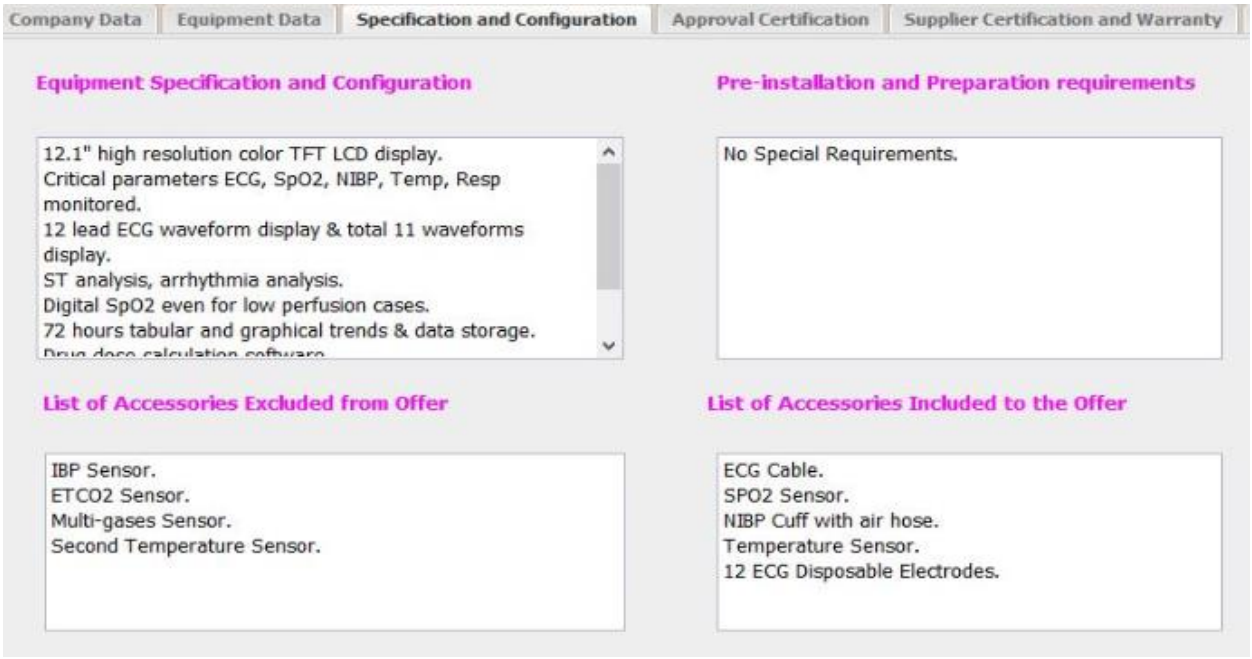

Figure5.6: Specifications and configurations.

- The fourth page is for approval certification for the device and its all accessories.

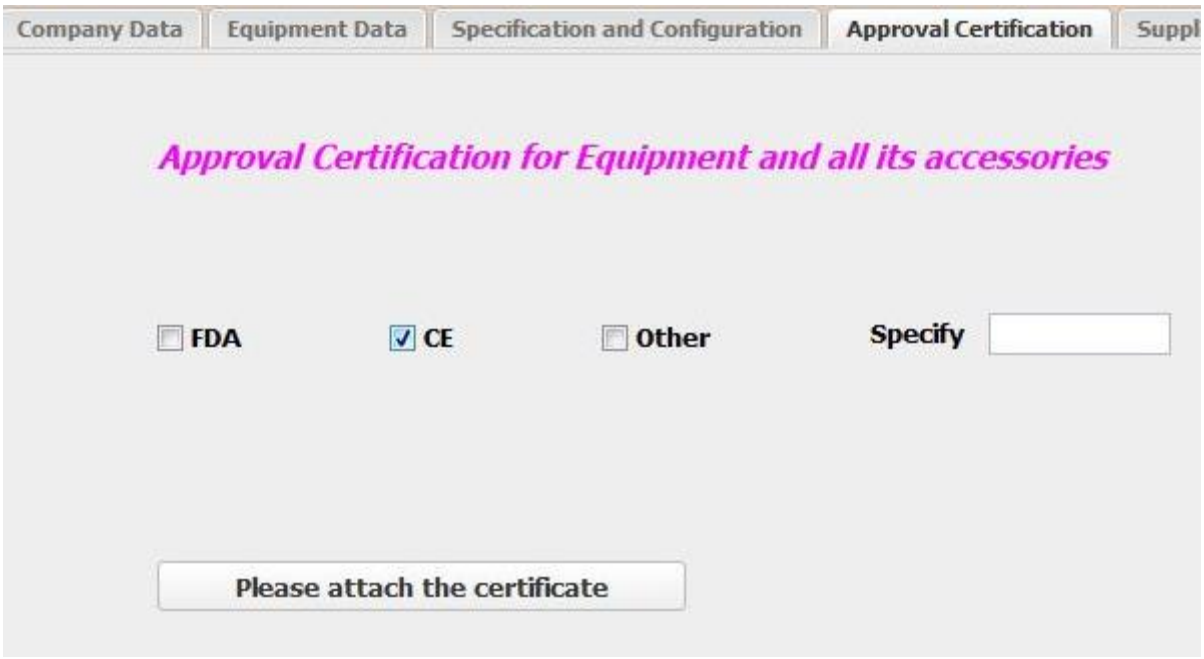

Figure5.7: Approval certification.

- The fifth page is for supplier kind and warranty.

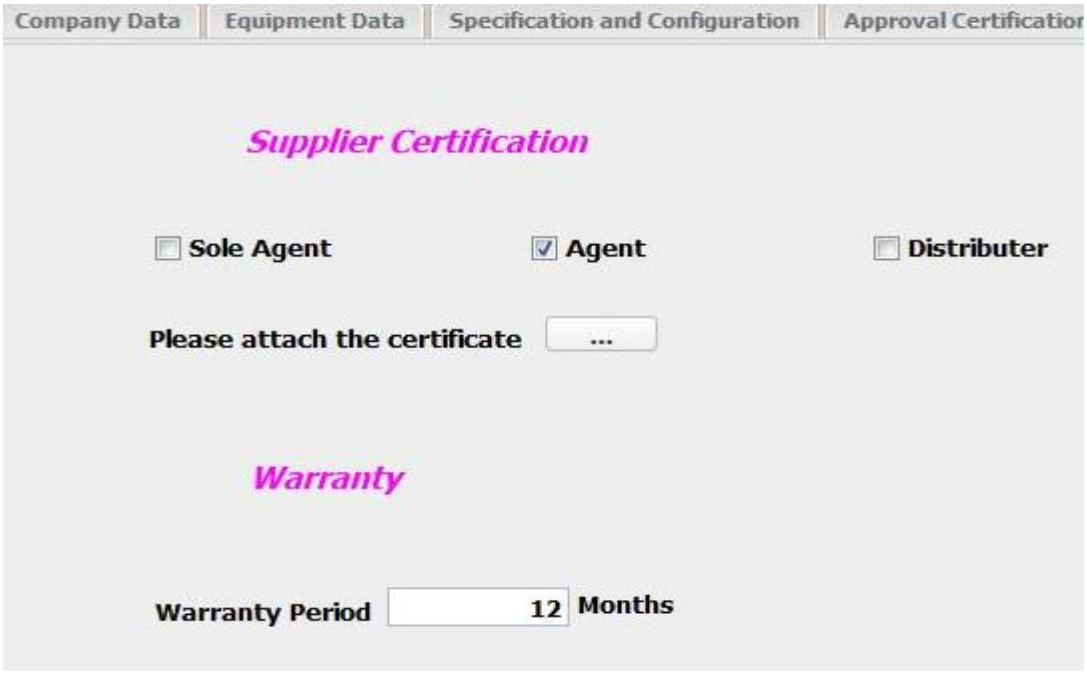

Figure5.8: Supplier and warranty

- Installation and technical support after warranty period is entered in the sixth page.

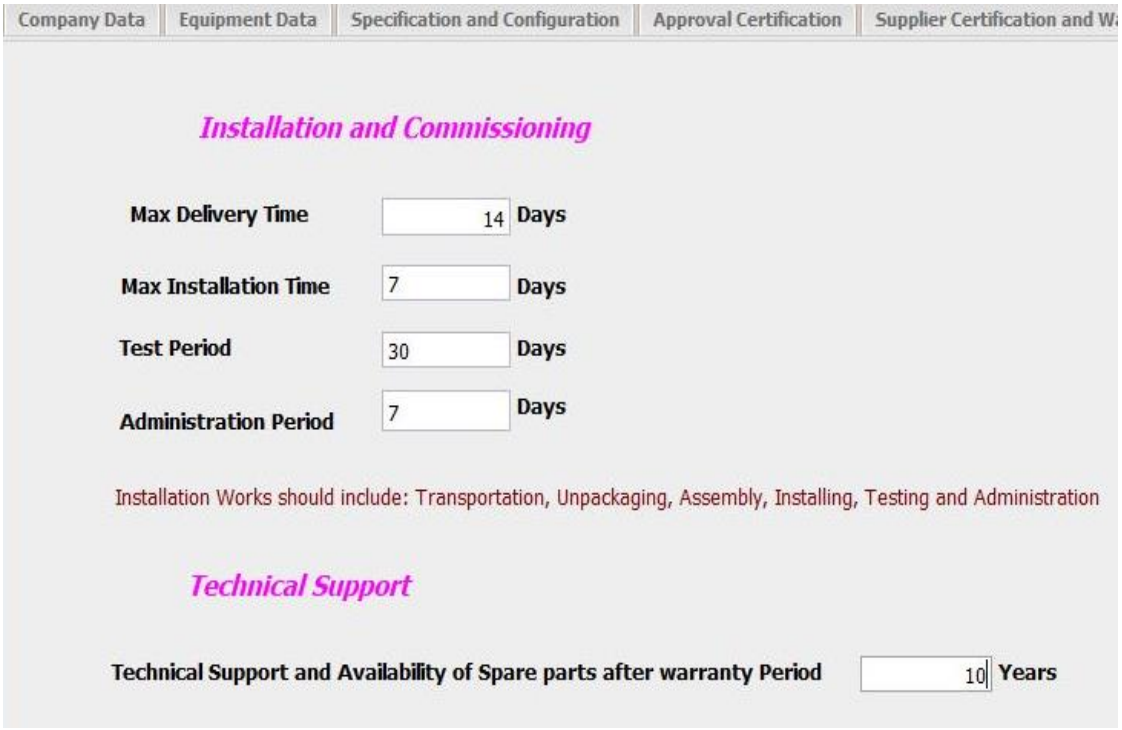

Figure5.9: Installation and technical support.

- The last page is for abroad trainig for biomedial engineers.

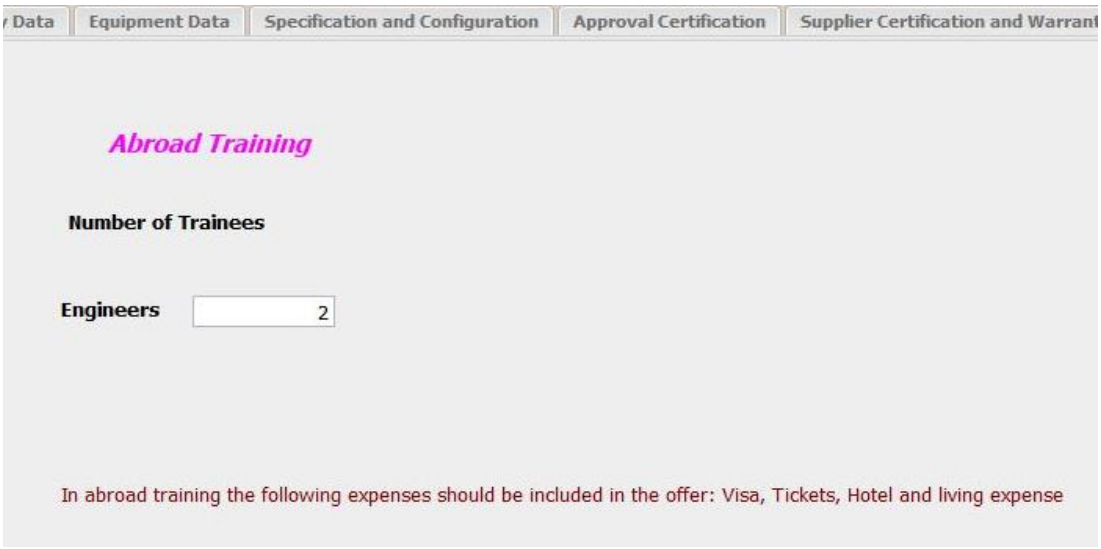

Figure5.10: Abroad training.

The administrators of the program need to enter user name and password then they have two pages; one for evaluating device configuration & specifications and the other one is for displaying results.

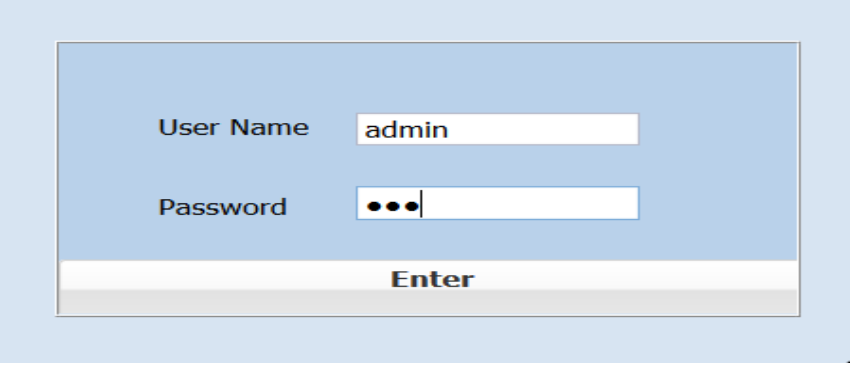

Figure5.11: User name and password.

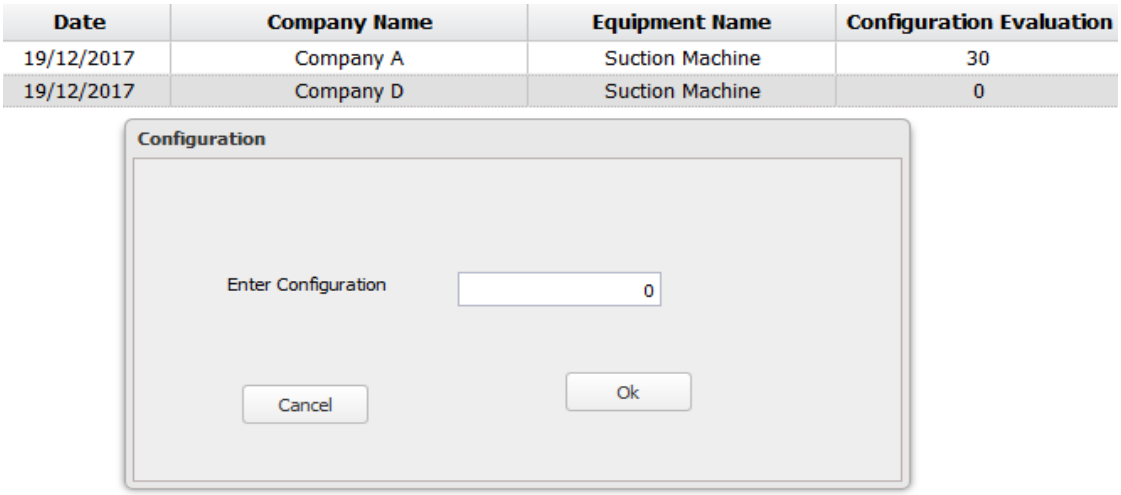

Figure5.12: configuration evaluation.

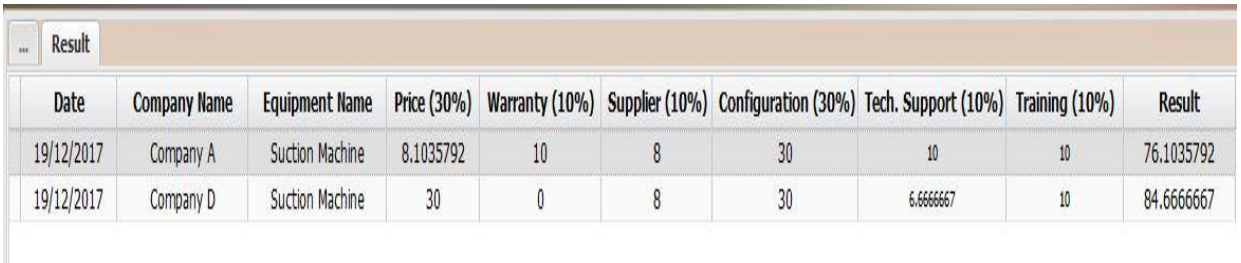

Figure5.13: Results Displaying.

5.2 Implementation:

The program was implemented in Ribat University hospital on a tender of seven medical equipments from five separated medical equipment companies for ICU department.
It had been implemented on local host for the reasons that we couldn't have permission to access the hospital web site and the tender was selective.
The selection requirements had been specified according to WHO Guiding principles for selecting medical devices and since there is no standard method for Weight percentage setting for every selection factor we followed Ribat university hospital system in Weight percentages distribution.
The following table (5.1) shows results of the implantation of the program. The rows represent the companies that competed in the tender and the columns show selection requirements percentages calculated using the following equations:

- for warranty:

Wy=X/Y*10

Wy: warranty point for Y
X: maximum warranty period (in months)
Y: calculated warranty period (in months)

- for technical support:

Ty=X/Y*10

Ty: technical support points for Y
X: maximum technical support period (in years)
Y: calculated technical support period (in years)

- for abroad training :

Ay=X/Y*10

Ay: abroad training points for Y
X: maximum abroad training (engineers)
Y: calculated abroad training (engineers)

- for price:

Py=X/Y*30

Py: price points for Y
X: minimum price (in SDG)
Y: calculated price (SDG)

- For supplier type the user can use between 3 different option with 3 different percentages.
- For the specification evaluation the administrator enters the evaluation points – percentages.
- The final result was calculated by summation of all selection requirements for each company.

table5.1: Tender Results.

Company	Equipment	Configurat -ion 30%	Price 30%	Supplier 10%	Warranty 10%	Technical support 10%	Training 10%	Final Result 100%
Company B	Patient Monitor	30	25.144	8	5	10	10	88.144
Company A	Patient Monitor	30	30	8	10	0	5	83
Company D	Patient Monitor	30	11.571	8	0	10	5	64.571
Company B	Infusion Pump	30	30	4	3.333	10	10	87.333
Company A	Infusion Pump	30	17.127	8	10	10	10	85.127
Company D	Infusion Pump	30	12.831	8	0	10	10	70.831
Company B	Syringe Pump	30	30	4	3.333	10	10	87.333
Company A	Syringe Pump	30	17.127	8	10	10	10	85.127
Company D	Syringe Pump	30	21.386	8	0	10	10	79.836
Company D	Suction Machine	30	30	8	0	6.666	10	84.666
Company A	Suction Machine	30	8.102	8	10	10	10	76.103
Company C	Ultrasound	30	30	4	10	10	10	94
Company E	Ultrasound	30	16.017	4	5	10	10	75.017
Company A	Ventilator	30	30	8	10	10	10	98
Company B	Defibrillator	30	30	4	10	10	10	94

Chapter Six

Discussion

The purpose of this study was to design and implement automated mechanism for medical devices procurement.

This study found that most healthcare institutions in Khartoum/Sudan have policies that are followed for the procurement of medical devices. Some are good enough to take into account many considerations such as user specifications, reliability, safety and after sales services and others are not.

The results obtained in this study show that biomedical engineers are involved in the procurement process in the majority of healthcare institutions. Existence of qualified and well trained biomedical engineer in medical device procurement process is very important for determining specification and configuration and other selection factors.

Only a few healthcare facilities insist to purchase from Agent Company. Procuring from agent company can guarantee better technical support and after sales services like warranty and availability of Consumables, accessories and spare parts for whole medical devices lifespan.

With the lack of financial resources often some healthcare institutions would accept a degraded medical device quality in order to lower the cost.

Buying the cheapest items can be a false economy, because they may need repairing or replacing more frequently. Medical devices must be of sufficiently high quality in terms of: Performance, Safety and Materials & design.

Unfortunately more than quarter of the engineers sampled in this study does not consider approval certification as an important part of procurement process. All medical devices should meet international, regional or national safety and performance standards.

The regulation of medical devices should maintain a balance between ensuring device safety, quality and effectiveness and providing the public with timely access to medical devices and preventing the entrance of unsafe or ineffective devices into the healthcare organization.

It was observed that more than half of institutions purchase only from pre-qualified or known bidders. Open Tender is a transparent process which ensures that only the contractor with the best price and meeting all the technical requirements will win the tender while selective tender might not give a chance for new competitors to participate.

Generality of healthcare institutions obligate the vendor by procurement contract. Purchasers should carefully evaluate acquisition contracts to identify minimum volume commitments, service requirements, training that is included, user support, warranty provisions and accessories & spare parts pricing discounts.

Negotiation of these elements in the contract is required to guarantee that the best value and the lowest costs are obtained from the vendor.

Results indicate that improvement is needed in procuring required special maintenance tools and calibration and/or QC tools, where necessary to ensure the reliability, reproducibility and safety of the medical device.

However it was observed that the method used for offers sorting process is manual in most healthcare institutions.

Proper implementation of automated medical devices procurement system with considering all parameters of selection leads to an efficient and safe use of medical equipment increases its lifetime and saves a lot of time & effort as well as budget for healthcare organization.

Chapter Seven

Conclusion and Recommendations

7.1 Conclusion:

Identification of appropriate medical device, and its acquisition and utilization, require massive investment, and related decisions must be made carefully to ensure the best match between the supply of the medical device and health system needs.
The goal of this project was to Design and implement automated mechanism for medical devices procurement. Data were collected from various sources such as former researches, expert's opinions and questionnaire and processed with aid of statistical analysis to get convenient view for designing.
The findings from the data collected revealed that most healthcare institutions do not have proper mechanisms for procurement of the medical devices.
Implementation of the medical device procurement program by qualified and well trained staff obtained good results by providing high accuracy in calculations and saving a lot of time and effort.
So it can be included that the medical device procurement program is suitable for healthcare institutions for acquiring new devices especially when applied on big quantity of medical devices.

7.2 Recommendation:

- Implementing the program in health organization's website.
- Activating attachment buttons.
- Calculating configuration percentages by equation to make the system full automated.
- Finding another equation for price percentages calculation to avoid magnification issues.
- Considering physicians and nurses training as selection requirement.
- Connecting the program to the medical equipment management system.
- Describing medical device procurement situation in Sudan and discussing local guidelines.

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Appendices

Appendix (A)

Form of questionnaire:

Sudan University of science and technology
College of Graduate studies - Biomedical Engineering Department
Questionnaire about medical devices procurement

1- Is there a certain policy that is followed for the procurement of medical devices?

☐ Yes ☐ No

2- Who performs the procurement operation?

☐ Individuals ☐ Team

3- In case a team performs the procurement, does that team include a biomedical engineer?

☐ Yes ☐ No

4- The provider from which the medical equipments are purchased is:

☐ Agent company ☐ Distributer companies

☐ Others; Specify……..

5- Do you have forecasting plan?

☐ Yes ☐ No

6- What method is used to procurement?

☐ Single Bid ☐ Selective ☐ Open bid

☐ Others; Specify……..

7- Is quality certification an important part of the purchase operation?

☐ Yes ☐ No

8- If yes, which quality certificates are accredited?

☐ Any ☐ Specific; Specify……..

9- When choosing an offer from multiple offers what is the weight of each selection criteria?

☐ Technical …..% ☐ Technological…..%

☐ Financial……% ☐ Others;…% Specify……

10- How is the offers sorting and selection process is performed?

☐ Manual ☐ Automated ☐ Semi-automated

11- If automated/semi-automated what is the programming language used?

☐ Excel ☐ Others, Specify……..

12- Do you purchase the medical devices by contract?

☐ Yes ☐ No

13- Are the following points included in the contract?

☐ Warranty ☐ Training

☐ Provision of spare parts & technical support after warranty

14- Do you purchase special maintenance tools with the medical equipment?

☐ Yes ☐ No

15- Do you purchase calibration and quality control tools with the medical equipment?

☐ Yes ☐ No

Appendix (B)

Program Code:

```
unit data_module;
interface
uses
  SysUtils, Classes, DB, MemDS, DBAccess, MyAccess;
type
  TDataModule1 = class(TDataModule)
    MyConnection1: TMyConnection;
    MyQuery1: TMyQuery;
    DataSource1: TDataSource;
    MyQuery1c_name: TStringField;
    MyQuery1loc: TStringField;
    MyQuery1tel: TStringField;
    MyQuery1email: TStringField;
    MyQuery1equip_name: TStringField;
    MyQuery1made: TStringField;
    MyQuery1origin: TStringField;
    MyQuery1model: TStringField;
    MyQuery1qty: TIntegerField;
    MyQuery1unit_price: TFloatField;
    MyQuery1total_price: TFloatField;
    MyQuery1specif: TMemoField;
    MyQuery1list_access_in: TStringField;
    MyQuery1list_access_ex: TStringField;
    MyQuery1pre_req: TStringField;
    MyQuery1fda: TIntegerField;
    MyQuery1ce: TIntegerField;
    MyQuery1other: TIntegerField;
    MyQuery1specify: TStringField;
    MyQuery1s_sgent: TIntegerField;
    MyQuery1agent: TIntegerField;
    MyQuery1distributer: TIntegerField;
    MyQuery1w_periiod: TIntegerField;
    MyQuery1field24: TStringField;
    MyQuery1max_d_time: TIntegerField;
    MyQuery1max_install_time: TStringField;
    MyQuery1test_period: TStringField;
    MyQuery1admin_period: TStringField;
    MyQuery1tech_support: TFloatField;
    MyQuery1o_manual: TIntegerField;
    MyQuery1s_manual: TIntegerField;
    MyQuery1engineers: TIntegerField;
    MyQuery1doctors: TIntegerField;
    MyQuery1tech: TIntegerField;
    MyQuery1local: TIntegerField;
    MyQuery1aboard: TIntegerField;
    MyQuery1a_date: TDateField;
```

```
    MyQuery2: TMyQuery;
    DataSource2: TDataSource;
    MyQuery2name: TStringField;
  private
    { Private declarations }
  public
    { Public declarations }
  end;
function DataModule1: TDataModule1;
implementation
{$R *.dfm}
uses
  UniGUIVars, uniGUIMainModule, MainModule;
function DataModule1: TDataModule1;
begin
  Result := TDataModule1(UniMainModule.GetModuleInstance(TDataModule1));
end;
initialization
  RegisterModuleClass(TDataModule1);
end.
unit Main;
interface
uses
  Windows, Messages, SysUtils, Variants, Classes, Graphics,
  Controls, Forms, Dialogs, uniGUITypes, uniGUIAbstractClasses,
  uniGUIClasses, uniGUIForm, uniGUIBaseClasses, uniLabel, uniButton, uniEdit,
  uniDBEdit, uniPanel, uniPageControl, uniMemo, uniDBMemo, uniCheckBox,
  uniDBCheckBox, uniFileUpload, StdCtrls, uniMultiItem, uniComboBox,
  uniDBComboBox, uniDBLookupComboBox;
type
  TMainForm = class(TUniForm)
    UniPageControl1: TUniPageControl;
    UniTabSheet1: TUniTabSheet;
    UniLabel2: TUniLabel;
    UniDBEdit1: TUniDBEdit;
    UniLabel3: TUniLabel;
    UniLabel4: TUniLabel;
    UniLabel5: TUniLabel;
    UniDBEdit2: TUniDBEdit;
    UniDBEdit3: TUniDBEdit;
    UniDBEdit4: TUniDBEdit;
    UniTabSheet2: TUniTabSheet;
    UniLabel6: TUniLabel;
    UniLabel7: TUniLabel;
    UniLabel8: TUniLabel;
    UniLabel9: TUniLabel;
    UniLabel10: TUniLabel;
    UniLabel11: TUniLabel;
    UniLabel12: TUniLabel;
    UniDBEdit5: TUniDBEdit;
```

UniDBEdit6: TUniDBEdit;
UniDBEdit7: TUniDBEdit;
UniDBEdit8: TUniDBEdit;
UniDBEdit9: TUniDBEdit;
UniDBEdit10: TUniDBEdit;
UniDBEdit11: TUniDBEdit;
UniTabSheet3: TUniTabSheet;
UniLabel1: TUniLabel;
UniLabel14: TUniLabel;
UniLabel15: TUniLabel;
UniLabel16: TUniLabel;
UniDBMemo1: TUniDBMemo;
UniTabSheet4: TUniTabSheet;
UniLabel17: TUniLabel;
UniLabel18: TUniLabel;
UniDBCheckBox1: TUniDBCheckBox;
UniDBCheckBox2: TUniDBCheckBox;
UniDBCheckBox3: TUniDBCheckBox;
UniDBEdit15: TUniDBEdit;
UniTabSheet5: TUniTabSheet;
UniLabel25: TUniLabel;
UniDBCheckBox4: TUniDBCheckBox;
UniDBCheckBox5: TUniDBCheckBox;
UniDBCheckBox6: TUniDBCheckBox;
UniLabel20: TUniLabel;
UniLabel22: TUniLabel;
UniLabel24: TUniLabel;
UniLabel26: TUniLabel;
Years: TUniLabel;
UniDBEdit16: TUniDBEdit;
UniTabSheet6: TUniTabSheet;
UniLabel29: TUniLabel;
UniLabel30: TUniLabel;
UniDBEdit17: TUniDBEdit;
UniLabel31: TUniLabel;
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UniLabel33: TUniLabel;
UniLabel34: TUniLabel;
UniLabel36: TUniLabel;
UniLabel37: TUniLabel;
UniLabel39: TUniLabel;
UniLabel41: TUniLabel;
UniDBEdit18: TUniDBEdit;
UniDBEdit19: TUniDBEdit;
UniDBEdit20: TUniDBEdit;
UniDBEdit21: TUniDBEdit;
UniDBEdit22: TUniDBEdit;
UniTabSheet7: TUniTabSheet;
UniLabel44: TUniLabel;
UniDBCheckBox8: TUniDBCheckBox;

```
    UniPanel1: TUniPanel;
    UniButton1: TUniButton;
    UniButton2: TUniButton;
    UniMemo1: TUniMemo;
    UniButton3: TUniButton;
    UniButton4: TUniButton;
    UniDBEdit24: TUniDBEdit;
    UniDBEdit25: TUniDBEdit;
    UniLabel45: TUniLabel;
    UniLabel42: TUniLabel;
    UniLabel40: TUniLabel;
    UniLabel38: TUniLabel;
    UniLabel35: TUniLabel;
    UniLabel47: TUniLabel;
    UniDBMemo2: TUniDBMemo;
    UniDBMemo3: TUniDBMemo;
    UniDBMemo4: TUniDBMemo;
    UniLabel23: TUniLabel;
    UniLabel43: TUniLabel;
    UniDBCheckBox7: TUniDBCheckBox;
    UniLabel21: TUniLabel;
    UniDBLookupComboBox1: TUniDBLookupComboBox;
    UniDBEdit26: TUniDBEdit;
    UniLabel46: TUniLabel;
    UniDBEdit23: TUniDBEdit;
    procedure UniButton1Click(Sender: TObject);
    procedure UniFormShow(Sender: TObject);
    procedure UniButton3Click(Sender: TObject);
  private
    { Private declarations }
  public
    { Public declarations }
  end;
function MainForm: TMainForm;
implementation
{$R *.dfm}
uses
  uniGUIVars, MainModule, uniGUIApplication,data_module;
function MainForm: TMainForm;
begin
  Result := TMainForm(UniMainModule.GetFormInstance(TMainForm));
end;
procedure TMainForm.UniButton1Click(Sender: TObject);
begin
if UniDBEdit1.Text='' then
UniDBEdit1.Color:=clRed
else
if UniDBEdit2.Text='' then
UniDBEdit2.Color:=clRed
else
```

```
if UniDBEdit3.Text='' then
UniDBEdit3.Color:=clRed
else
if UniDBEdit4.Text='' then
UniDBEdit4.Color:=clRed
else
begin
DataModule1.MyQuery1.Open;
DataModule1.MyQuery1a_date.AsDateTime:=Date;
DataModule1.MyQuery1.Post;
MessageDlg('Data Saved',mtInformation,[mbok]);
end;
end;
procedure TMainForm.UniButton3Click(Sender: TObject);
begin
DataModule1.MyQuery1.Open;
DataModule1.MyQuery1.insert;
end;
procedure TMainForm.UniFormShow(Sender: TObject);
begin
if FileExists('C:\Project\Server.inf') then begin
     unimemo1.clear;
     unimemo1.lines.loadfromfile('C:\Project\Server.inf');
     if unimemo1.lines.count = 4 then begin
       DataModule1.MyConnection1.Connected := False;
       DataModule1.MyConnection1.server    := unimemo1.lines.strings[0];
       DataModule1.MyConnection1.Database  := unimemo1.lines.strings[1];
       DataModule1.MyConnection1.Username  := unimemo1.lines.strings[2];
       DataModule1.MyConnection1.Password  := unimemo1.lines.strings[3];
       DataModule1.MyConnection1.Connected := True;
       DataModule1.MyQuery1.Open;
             DataModule1.MyQuery2.Open;
       //*******************************
       DataModule1.MyQuery1.insert;
       //*******************************
     end else begin
      MessageDlg('Server Connection Error',mtError,[mbOK]);
      Application.Terminate;
     End;
     uniMemo1.Clear;
  end else begin
     MessageDlg('Server Connection Error',mtError,[mbOK]);
     Application.Terminate;
  End;
end;
initialization
  RegisterMainFormClass(TMainForm);
end.
unit MainModule;
interface
```

```
uses
  uniGUIMainModule, SysUtils, Classes;
type
  TUniMainModule = class(TUniGUIMainModule)
  private
    { Private declarations }
  public
    { Public declarations }
  end;
function UniMainModule: TUniMainModule;
implementation
{$R *.dfm}
uses
  UniGUIVars, ServerModule, uniGUIApplication;
function UniMainModule: TUniMainModule;
begin
  Result := TUniMainModule(UniApplication.UniMainModule)
end;
initialization
  RegisterMainModuleClass(TUniMainModule);
end.
unit ServerModule;
interface
uses
  SysUtils, uniGUIServer, uniGUIMainModule, uniGUIApplication;
type
  TUniServerModule = class(TUniGUIServerModule)
  private
    { Private declarations }
  protected
    procedure FirstInit; override;
  public
    { Public declarations }
  end;
function UniServerModule: TUniServerModule;
implementation
{$R *.dfm}
uses
  UniGUIVars;
function UniServerModule: TUniServerModule;
begin
  Result:=TUniServerModule(UniGUIServerInstance);
end.
procedure TUniServerModule.FirstInit;
begin
  InitServerModule(Self);
end;
initialization
  RegisterServerModuleClass(TUniServerModule);
end.
```