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Computerized Inspection Program and Procedures for Medical Devices (CIPP)

برنامج محوسب للتفتيش و الإجراءات للأجهزة الطبية

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بسم الله الرحمن الرحيم

﴿ وَقُلِ اعْمَلُواْ فَسَيَرَى اللّهُ عَمَلَكُمْ وَرَسُولُهُ وَالْمُؤْمِنُونَ وَسَتُرَدُّونَ
إِلَى عَالِمِ الْغَيْبِ وَالشَّهَادَةِ فَيُنَبِّئُكُم بِمَا كُنتُمْ تَعْمَلُونَ ﴾

صدق الله العظيم

سورة التوبة الآية (105)

DEDICATIONS

The words and measures can never express my deepest gratitude to my parents. They have been a force of strength all along, and without them it would have been an uphill task for me to complete this work.

Last but not least, we are deeply indebted to our brothers, sisters and our friend; their incessant support made us achieve new heights in life and built our character.

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Our grateful thanks to Allah for guiding us and giving us the strength to complete this project with his mercy, kindness and blesses. Thanks are progressed generally to all the staff of bio-medical engineering department at Sudan University of science and technology, and specifically to D. Mawia Ahmed Hassan. Gratitude and thanks to Special thanks to our families who supported us all through the way, and provided us with their kindness and prayers.

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ABBREVIATION:

QA	Quality assurance
QC	Quality control
PM	Preventive maintenance
CM	Corrective maintenance
IPM	Inception preventive maintenance
FDA	Food and drug administration
WHO	World health organization
ISO	International organization for standardization
IEC	International electro technical commission
MEMP	Medical Equipment Management Program
MEQAP	Medical Equipment Quality Assurance Program
CIPP	Computerized inspection program and procedures
CMMS	Computerized Management Maintenance system
GUI	Graphic user interface
SN	Serial number
CN	Control number
SSMO	Sudanese standards and metrology organization

ABSTRACT

Hospitals and health care organizations possess a large number of medical devices and equipments, most of these devices and equipments are very complex and designed with modern technology. Hospitals must insure that their critical medical devices are safe, accurate, reliable and operating at the required level of performance. Equipments should be properly maintained and kept in a good running condition in order that they fulfill the objectives for which they were purchased. Even though the importance, the application of all inspections, maintenance and optimization models to medical devices is fairly new.

Equipments failure may not always be apparent to clinical staff. Therefore they should be inspected periodically. Scheduled inspections help to ensure the safety and efficiency of medical equipments. In this study the software tool is developed to implement a risk oriented prioritization of devices for preventive maintenance inspections, were devices with higher criticality score can be assigned a higher priority maintenance management program. The data base contain the equipment inventory, and related data files.

First established an effective, efficient planned inspection and preventive maintenance system, and then collected data of all equipments in hospitals or health care organizations entered to the system.

The reports based on the inspection results, help in determining better scheduling than constant sweeping of all the devices.

المستخلص

المستشفيات و المؤسسات الصحية تمتلك عدد كبير من الأجهزة و المعدات الطبية, معظم هذه الأجهزة و المعدات متطورة و صممت بتكنولوجيا حديثة جدا. و يجب أن تضمن المستشفيات أجهزتها الطبية الحرجة أن تكون آمنة ودقيقة وموثوقة وتعمل بالمستوى المطلوب من الأداء. ينبغي الحفاظ على المعدات بشكل صحيح و المحافظة عليها في حالة تشغيل جيدة من أجل أن تحقق الأهداف التي من أجلها تم شرائها, على الرغم من أن أهمية تطبيق جميع نماذج الفحص والصيانة الأمثل للأجهزة الطبية يعتبر جديد الى حد ما. فشل المعدات قد لا يكون دائما واضح للفريق الطبي, وبالتالي يجب عمل فحص دوري للأجهزة. عمليات الفحص المقررة تساعد على ضمان سلامة وفعالية المعدات الطبية. في هذه الدراسة, تم تطوير أداة برمجية لتطبيق أولويات موجهة المخاطر للأجهزة لفحوصات الصيانة الوقائية حيث أن الأجهزة التي لها معدل خطر عالي تكون أكثر أولوية في برنامج إدارة الصيانة. حيث تتضمن قاعدة البيانات قائمة محتويات المخزون و المعدات, والملفات ذات الصلة بالبرنامج.

في البداية يتم تحديد نظام تفتيش وصيانة وقائية فعال ومن ثم يتم جمع بيانات المعدات البيانات من المستشفيات وإدخالها الى النظام .

يتم عمل تقارير بناء على نتائج فحص الأجهزة, حيث يساعد ذلك على تحديد جدولة أفضل بدلا من المسح الشامل للأجهزة في كل مرة .

CHAPTER ONE

INTRODUCTION

1.1 project introduction:

The increase of need for medical devices in the eighties, had led to enter many medical devices without control or observation and they didn't do their main purpose they brought for. In the nineties also there was activation in health care institutions which owned many medical devices but with no control for how the performance is, no continuity assurance and no control for quality performance. Beside that the medical devices marketing became very popular including devices that entered by charity or welfares and all o f those were without control. In this century many medical institutes tried to establish the basics to enter a medical device into health institutions such as the FDA, Central medical supplies public corporation, Sudan atomic energy commission and SSMO, but there have not been satisfied or good enough basics to control and observe medical devices.

Cost-effective and efficient maintenance decisions could be made after thoroughly understanding, implementing and leading maintenance excellence in healthcare organizations. Maintenance excellence is the balance of performance, risk, resource inputs and cost to reach to an optimal solution (Campbell and Jardine, 2001).

Unnecessary and excessive preventive maintenance could be also loss-making likewise inadequate level of maintenance. The time, which is spent doing the unnecessary preventive maintenance, is robbing an organization of a fraction of one of its most vital resources (Keil, 2008).

Also not having the basics to control devices led to waste large amounts of money and serious health problems sometimes. Not having the wanted benefit from the medical device by not using it correctly leads to: shortening the device life time and increase the need to buy new devices continually, the manufactures institutions which provide the training, the spare parts or the maintenance will have no benefits and may not have clear plans for the health institution so they might have the devices but with no correct basic control conditions.

Hospitals and healthcare organizations must ensure that their critical medical devices are safe, accurate, reliable and operating at the required level of performance. To achieve these objectives, hospitals must establish and regulate a Medical Equipment Management Program (MEMP) which describes risk management of medical equipment. Inspection and preventive maintenance is a fundamental aspect of such a program and it should be reviewed and improved continuously in order to keep up with the pace of today's technological improvement of medical equipment, as well as increasing expectations of healthcare organizations. [1]

To fix the entry of medical devices to health care institutions correctly there are many things must be provided as:

1. Oblige health care institutes to have a QC unit under a central governmental observation to ensure the efficiency of medical devices and adjust performance maintenance procedures.
2. Governmental health care institutions should establish its standards compatible to its needs and benefits.
3. Making sure those healthcare institutions put its conditions clearly for the producing institutes to ensure commitment with the buying

contracts to have the medical devices work with high quality until the end of the device type.

4. Qualify workers on operating and maintenance for medical devices to have the maximum benefits from workers abilities.
5. Put reasonable budget to provide enough maintenance equipment's and enough spare parts.

Medical equipment quality control QA is part of an overall medical equipment management program for a healthcare facility or system. A complete program also includes corrective maintenance or repair, equipment control, asset management, health care technology planning, education, and activities directed toward improving medical device-related patient safety. [2]

We take into consideration in our program the advances in device reliability, reduced preventive maintenance requirements, and internal device surveillance (self-test) along with changes in standards.

1.2 Project problem statement:

There is no clear program of inspection for medical devices in Sudan to help those responsible for establishing and managing medical equipment QA program and staff performing inspections and device testing.

1.3 Project 0bjectives:

1. Establishing and managing a medical equipment quality assurance (QA) program.

2. To present detailed procedures for inspections, preventive maintenance, safety pollution and performance testing.

1.4 Project organization:

Chapter one consists of introduction layout, problem statement and objective. Chapter two contains the theoretical background. The literature review described in chapter three. Chapter four deal with the methodology of data collection and system design. The results and discussion are described in chapter five. Chapter six deal with the conclusion and future work. Finally chapter seven includes the references.

CHAPTER TWO

LITERATURE REVIEWS

The acceptance procedure of medical devices for usage in health care facilities is of a significant effect on patient's treatment quality, personnel safety and maintenance cost. An acceptance inspection is needed when new or repaired medical devices are received by the institute. It may discover equipment failure or dysfunction, and thus prevent false diagnosis, an inefficient or dangerous treatment, risking the patient or staff. Nevertheless, a general and comprehensive inspection procedure of medical devices has not yet been described, and there are no publications regarding the quality control of the process. We therefore suggest a quality controlled inspection process, which can be easily applied in hospitals and sick funds. The process refers to portable and non-mobile, new and repaired medical equipment. The means and instruments needed for the process application are detailed.

Medical devices which do not function properly may cause the lost of human life - may it be done by causing a direct damage or by leading to an error in the diagnosis of a disease. For example, devices which are used in nuclear medicine may hazard not only the patient but also the medical staff. We should remember this when developing an inspection procedure for medical devices and to improve our process continuously. The general procedure described in this work refers to a variety of device types and may be easily adopted to any institute needs and applied in biomedical/clinical engineering departments of hospitals, sick funds, and military medical corps clinics.[3]

In this paper, we present a multi-criteria decision-making model to prioritize medical devices according to their criticality. Devices with higher criticality scores can be assigned a higher priority in a maintenance management program. A computerized medical management system is described. The results demonstrate that it is a useful tool in tracking device inventory and maintenance history. Also risk classes have been designed for medical devices based on the time of testing, risk must be identified in relation to patient and personal staff. The results of this paper take into consideration the advances in device reliability, reduced preventive maintenance requirements, and internal device surveillance (self test) along with changes in standards.

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The importance of maintenance activities is to effectively manage the equipment; this task necessitates complex information about the medical device. Thus it is necessary to make an archive of what happened in the past, to tell if the situation improves and you learn from previous situations.

Finally, record maintenance activities provide the staff valuable technical information and evidence that they can use when they need argues need help or additional resources. Data base system maintenance helps keep health service records of repairs and other actions. [4]

The plant working conditions and the repair strategies play an important role in maintaining the operating systems, operative for maximum duration i.e. optimal system availability. This can be accomplished only through performance evaluation and analysis of all the operating systems of the plant.

Most of the firms adopting ‘process‘ oriented manufacturing ,comprise of large complex engineering systems/subsystems which are arranged in series, parallel or a combination of both. Hence, it becomes imperative to have reliable systems for efficiency, long term survival and growth. Thus, all the workable engineering systems are expected to remain operative with the maximum efficiency for the maximum duration to ensure their reliable operation. [5]

This paper presents an analysis of software-related failures of medical devices that caused no death or injury but led to recalls by the manufacturers. The analysis categorizes the failures by their symptoms and faults, and discusses methods of preventing and detecting faults in each category.

An important conclusion is that the use of many generally accepted quality practices is significant toward reduction of system failures. [6]
Electrical safety is a very important factor that needs to be tested: On newly acquired equipment prior to being accepted for use, during routine planned preventative maintenance and after repairs have been carried out on equipment.
Measurements and tests that were performed on every medical equipment of five fully operational operating theaters of a Greek hospital in Athens. Tests and measurements were performed according to the international protocols IEC 60601 and IEC 62353 (which is valid for medical devices). Results revealed that some multi-socket power lines, as well as some power cords were outside of the limits provided by the international protocols. Our results demonstrate that some multi-socket power lines, as well as some power cords were outside of the limits provided by the

international protocols. Failures were quite limited mainly due to hospital policy regarding EST tests, which are performed on a yearly basis for all biomedical equipment. It is highly profound that equipment found to be out of the EST limits should be tested more often than a yearly basis and proceed with their replacement once they do not pass the tests. [7]

Modern medical devices and equipment have become very complex and sophisticated and are expected to operate under stringent environments. Even though the importance, the application of all inspection, maintenance and optimization models to medical devices is fairly new. In Canada, most, if not all healthcare organizations include all their medical equipment in their maintenance program and just follow manufacturers' recommendations for preventative maintenance. Then, current maintenance strategies employed in hospitals and healthcare organizations have difficulty in identifying specific risks and applying optimal risk reduction activities. This paper addresses these gaps found in literature for medical equipment inspection and maintenance and reviews various important aspects including current policies applied in hospitals policies for better medical devices management in the future.

The most significant finding of this review is the need for further research in the field of maintenance of medical devices, as indicated by the gaps in existing research detailed above.[8]

CHAPTER THREE

THEORETICAL BACKGROUND

3.1 Inspection and maintenance of medical devices:

Medical devices are basic components of recent health services used for diagnosis, treatment, and monitoring of patients. On the other hand, the potential to manage and maintain medical equipment in most developing countries remain rather weak (World Health Organization, 1998). It is required to have useful methods and powerful management strategies to meet up the challenges of ever increasing number and use of medical devices.

Medical equipment maintenance can be divided into two major categories:

1. Inspection and preventive maintenance (IPM).
2. Corrective maintenance (CM).

Inspection preventive maintenance (IPM): IPM refers to all the scheduled activity necessary to ensure a piece of medical equipment is functioning correctly and is well maintained. IPM therefore includes inspection and preventive maintenance (PM).

Corrective maintenance (CM): A process used to restore the physical integrity, safety and/or performance of a device after a failure. Corrective maintenance and unscheduled maintenance are regarded as equivalent to the term repair. [9]

3.1.1 Definition of quality system:

Quality system is defined in ISO 8402 as: the organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

Inspections, Quality Control and Quality Assurance:

The development of quality management has been presented as an evolution from inspection, to quality control, to quality assurance. So we can start by giving The ISO 8402 definitions:

1. Inspection is:

Activities such as measuring, examining, testing, gauging one or more characteristics of product or service and comparing these with specified requirements to determine conformity.

2. Quality Control is:

The operational techniques and activities that are used to fulfill requirement for quality .

3. Quality Assurance is:

All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality .

Inspection is concerned with standard. On the other hand, Quality Control is concerned with feedback of the comparative information In order to regulate the process. Sentencing may also be involved, but ideally the limits are set so that the process can be adjusted before product from the process reaches the limit where it has to be rejected. Both inspection and quality control concentrate their attention on the processes of creating the product or service Quality assurance addresses the whole of Quality loop. It attempt to anticipate and prevent errors at all points in the organization which could have an impact on the Quality of the complete, delivered package associated with the product or services.[10]

3.1.2 Medical Equipment Classifications:

The Food and Drug Administration (FDA) has established classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialties referred to as panels. Each of these generic types of devices is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device. The three classes and the requirements which apply to them are:

1. Class I General Controls

- With Exemptions
- Without Exemptions

2. Class II General Controls and Special Controls

- With Exemptions
- Without Exemptions

3. Class III General Controls and Premarket Approval

In addition, classification is risk based, that is, the risk the device poses to the patient and/or the user is a major factor in the class it is assigned. Class I includes devices with the lowest risk and Class III includes those with the greatest risk. [11]

European Union classification of medical devices:

All medical devices are placed into one of four graduated categories, using the classification rules. It is considered more feasible, economically and justifiably, to categorize medical devices rather than all of them being subject to the rigorous conformity assessment procedures. The categories are:

- Class I
- Class IIa
- Class IIb
- Class III, with Class III ranked as the highest.

Considerations for classification include the duration of contact with the body, degree of invasiveness and local versus systemic effect. The highest possible class applies if a device can be classified according to several rules. [12]

Canadian classification of medical devices:

Similar to the European Union, Health Canada applies a four-tier classification system to medical devices according to their risk to the human body, with Class I representing the lowest risk to the human body and Class IV representing the highest risk.

Medical device classifications are determined by the Canadian Risk-Based Classification System (RBCS), under the auspices of the Therapeutic Products Division (TPD) of Health Canada. If a medical device can be classified in more than one class, the higher class applies. [13]

3.1.3. Essential Medical Equipment:

Basic medical equipment is commonly used in the healthcare organizations. It is helpful to present primary healthcare to the public. World Health Organization (WHO) classifies essential medical equipment in four main categories based on the use of the equipment for a specified health service delivery (World Health Organization, 1998).

Each individual hospital authorities decide which type and what number of these devices are required for their own health service purposes.

The main categories of World Health Organization (WHO) are:

1. General electro-medical equipment

- Portable electrocardiograph
- External defibrillator
- Portable anesthesia unit
- Respirator
- Dental chair unit
- Suction pump
- Operating theatre lamp
- Diathermy unit

2. Laboratory equipment

A variety of laboratory equipment is used for analysis or measurement purposes.

- Microscope
- Blood counter

- Analytical balance
- Colorimeter/spectrophotometer
- Centrifuge
- Water bath
- Incubator/oven
- Refrigerator
- Distillation and purification apparatus

3. Diagnostic imaging equipment

It is used to take pictures, which help clinicians to diagnose a patient's medical condition (McKay, 1986).

- Diagnostic X-ray equipment
- Ultra-sound equipment

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4. Other support equipment

- Operating theatre table
- Delivery table
- Autoclave- for general sterilization.
- Small sterilizer-for specific services (e.g., dentistry)
- Cold chain and other preventive medical equipment

- Electrical generator
- Electrical power regulator
- Air conditioner, dehumidifier
- Refrigerator
- Ambulance-four-cylinder diesel, four-wheel drive vehicle equipped with medical equipment for emergencies; complete accessories, spare tires and tools
- Gynecological examination table
- Small, inexpensive equipment and instruments.[1]

3.2. Medical Equipment Management:

Medical Equipment Management Program (MEMP) is established in hospitals to provide safe and reliable operation of medical equipment and promote its effective utilization (Stifle, 2009). This program defines procedures and policies to manage activities related to medical equipment, from their selection and acquisition to decommission. MEMP ensures that devices can provide reliable and accurate information to clinicians, operate safely for patients, and are used to their fullest capacity (University of Michigan Hospitals, 2010).

Several researches in area of reliable engineering for medical equipment mainly consider devices in their design or manufacturing stage and suggest many techniques to improve their reliability [1].

Device evaluation helps to determine how the device functions as well as its ability to provide reliable results. Devices have been evaluated to learn how they function. It is important to know the device limitations than to know how it performs against standard specifications. All devices have limitations, and the limitations must be identified prior to adopting the devices, to reduce the risks [14].

Until the past few years, the biomedical or clinical engineering program in most hospitals was so straightforward that the term program was inappropriate. In time past, the amount of medical instrumentation was such that the general hospital could employ a very small staff to look after its maintenance and minor repair problems.[15]

In order to achieve safety and efficiency, a comprehensive, well-designed Medical Equipment Management Program is mandatory.

Medical equipment quality assurance QA is part of an overall medical equipment management program for a healthcare facility or system. A complete program also includes**:**

- Corrective maintenance or repair
- Equipment control
- Asset management,
- Health care technology planning
- Education
- And activities directed toward improving medical device-related patient safety.[2]

3.2.1. Life Cycle of Medical Equipment:

The life cycle of medical devices should be thoroughly considered for effective management. Deficiencies in managing each stage of the life cycle, especially in the earlier phases can cause more problems in the succeeding stages.

A typical life cycle of medical equipment has these stages**:**

- Acquisition
- Delivery and Incoming Inspection
- Inventory and Documentation
- Installation, Commissioning and Acceptance
- Training of Users and Operators
- Monitoring of Use and Performance
- Maintenance
- Replacement and Disposal. [1]These stages are shown in Figure 3.1:

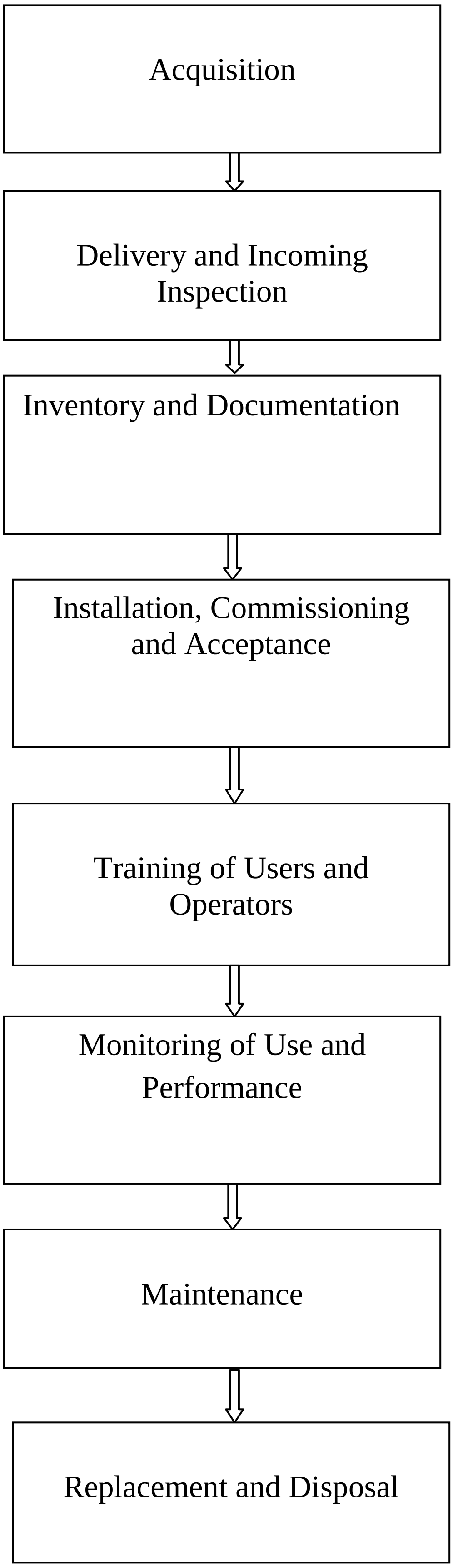


Figure 3.1: Life Cycle of Medical Equipment

3. 2.2.Joint Commission Standards for Medical Equipment:

In accordance with the life cycle phases of medical equipment, biomedical/clinical engineers should comply continuously with two primary Joint Commission medical equipment standards EC.02.04.01 and EC.02.04.03.

Standard EC.02.04.01 must be used by healthcare organizations to manage safety and security risks. Standard EC.02.04.03 presents guideline to inspects, tests, and maintains medical equipment. [1]

3.3. Preventive Maintenance of Medical Equipment:

Preventive maintenance is predetermined work performed to a schedule with the aim of preventing the sudden failure of equipment's components.

3.3.1 Real benefits of Preventive Maintenance (PM) system:

1. Increases operator, maintenance mechanic, and public safety.

2. Reduces downtime (increase uptime).

3. Increases equipment availability (available whenever needed).

4. Lowers cost/unit (output-cost per ton of coal, cost per widget, and cost per student).

5. Allows corrective maintenance to be scheduled when equipment is not needed.

6. Reduces damage to associated components.

7. Reduces the size and scale of repairs.

8. After a plant tour PM increases the chance a customer will give you business.

9. Reduces number of repairs.

10. increases equipment’s useful life.

11. Reduces investment by not needing spare or stand-by units.

12. Increase quality of output.

13. Reduces overtime for responding to emergency breakdown.

14. Increases accountability for all cash spent.

15. Increase potential exposure to liability.

16. Increase control over parts, reduces inventory level.

17. Insure that all parts are used for authorized purposes.

18. Reduces the chance for regulatory fines and sanctions.

19. Improve identification of problem areas to show where to focus attention.

20. Improves information available for equipment specification.

21. Lowers overall maintenance cost through better use of labor and materials. [16]

3.3.2 The two main parts of a PM:

1. Procedure: The procedure is the parent key to the schedule that is created using the PM easy form.

2. Schedule: The schedule is created second and lists the specific detailed to accomplish the procedure. It defines who, what, where and when of a procedure. [17]

Preventive maintenance (PM) schedule, service contracts, safety procedures, measurement points, multiple meters, inspection routes, specification data (name plate), equipment downtime, and related documentation. This equipment data is used for managing day-to-day operations and historical data that can be used to help make cost effective replace or repair decisions. The data can also be used to develop additional management information, such as building equipment downtime failure code hierarchies for use in maintenance management metrics. [18]

Predictive maintenance (Pd M):

By common agreement, the phrase predictive maintenance means Maintenance that that includes some instrument or technology. Properly, any instrument can be used for predictive maintenance if it is indeed used predicatively (predictive maintenance is about how you use the data). For example, predictive inspections can come from existing equipment used in new ways, including volt/ohm meters, mergers, and measuring instruments. All the predictive techniques should be listed on a task list and controlled by the PM system. [16]

Medical devices usually undergo several types of tests/inspections during their life cycles as described here (Atlas, 2008):

- Acceptance Test:

A series of qualitative and quantitative tasks designed to verify the safety and performance of newly received equipment, as well as conformity to applicable codes, regulations and standards.

- Operational Check:

Visual and operational check of the equipment’s safety and functionality typically performed at the beginning of the day or work period, or just before using equipment on a patient.

- Safety and Performance Inspection (SPI) :

A set of qualitative and quantitative tasks designed to verify the safety and performance of each piece of equipment by detecting potential and hidden failures and taking appropriate actions.

After accomplishing the acceptance test for a newly received device, SPIs are scheduled to be performed periodically. If any problem is found at inspection, corrective actions are taken to restore the device or its defective parts to an acceptable level. In addition, a set of failure preventive actions may be taken to prevent future failures and/or restore device function; these include part replacement, calibration, lubrication, etc. to address age or usage related deterioration. [1]

The PM/Inspection procedures should be based on need that includes the maintenance requirements of the device, risk classification, device function, and history of incidents. Maintenance and performance inspections do not prevent random failures, particularly related to electronic equipment and low risk devices do not need performance verification at the same frequency or intensity of higher risk devices. [1]

3.4. Using a risk-based assessment for establishing a medical equipment maintenance program:

The purpose of establishing risk-based maintenance intervals is to provide high-quality, cost-effective inspections based on risk and function, historical data on problems found, and the effect of maintenance on the reduction of problems.

The risk assessment should be done for each new device type during the incoming inspection when the device is added to the inventory. The device will then have a testing frequency assigned. After this is done, the maintenance history of the device should be monitored in order to evaluate the effectiveness of the maintenance program. [2]The process is shown in Figure 3.2

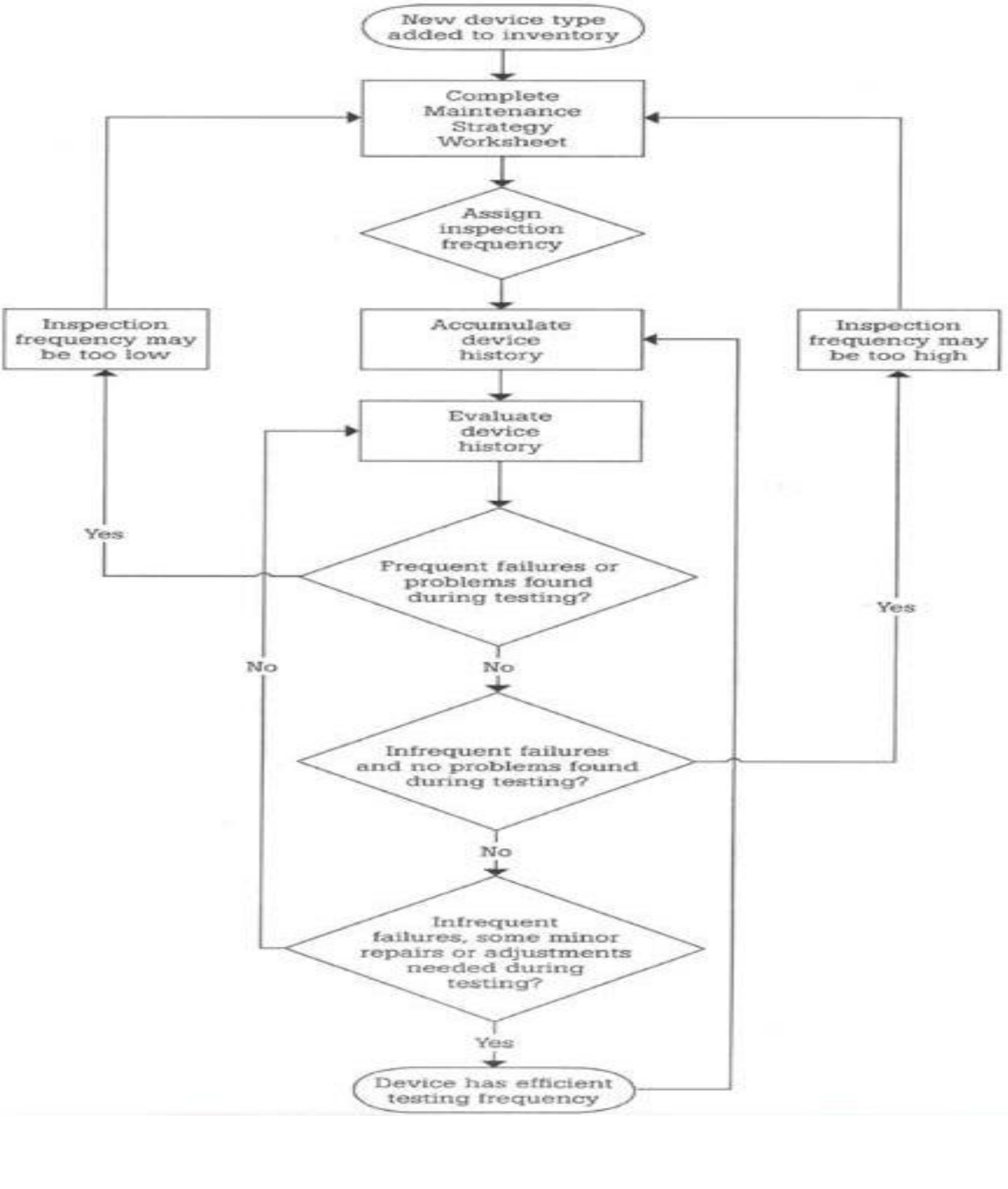


Figure 3.2: Logical diagram for assessing medical equipment

A 100% risk-free device is never attainable (T. Chan, personal communication) but a systematic assessment of potential risks associated with a medical device can significantly reduce potential harm to the user, manufacturer, and the medical device industry in general.

It is critically important that medical device manufacturers do not only implement a full risk assessment process of a medical device but also ensure that a solid risk management is also implemented (Medical Device School, 2005).[19]

3.5. Computerized Maintenance Management Systems:

A CMMS is a software package that contains a computer database of information about an organization's maintenance operations.

In health-care technology management, the CMMS is used to automate the documentation of all activities relating to medical devices, including equipment planning, inventory management, corrective and preventive maintenance procedures, spare parts control, service contracts, and medical device recalls and alerts. The collected data can be analyzed and used for technology management, quality assurance, work order control and budgeting of medical devices [14].

In order to effectively assist in the management and maintenance of medical equipment, a CMMS must comprehensively meet the needs of the user.

The following information should be tracked by the medical equipment management software

- **Basic device information:** Any medical equipment management software should track basic device information. At a minimum, the device type, manufacturer, model, and serial number should be tracked. This information is essential to the maintenance program.

- **Clinical use:** The clinical use of a device should be documented. Equipment used for life support needs to be given a higher priority for maintenance. Additionally, regulations on life support devices may be different.
- **Location:** This may be entered as the owner department or a physical location. The equipment location is used to find the equipment for maintenance. Also, the location is useful to break up the maintenance schedules by department.
- **Maintenance history:** A record should be kept of all maintenance performed on equipment, including scheduled maintenance, repairs, software upgrades, and incident investigations.

Dates of service should be included in this history.

- **Work coding:** A work order is generated for each maintenance event and a work order type is assigned to each work order. Work order coding is important in measuring the success of the maintenance program and for identifying areas that need to be addressed.[2]

A CMMS package integrates all medical equipment services into a database made up of fields, tables, modules and screens.

A CMMS can be used to:

• standardize and harmonize information within a health-care technology management program

• assist in the planning and monitoring of inspection and preventive maintenance and schedule and track repairs

• monitor equipment performance indicators such as mean time between failures, down time and maintenance costs for individual or equipment groups of the same model, type or manufacturer

• monitor clinical engineering staff performance indicators such as repeated repairs by the same staff member for the same problem, average down time associated with individuals, and productive work time for individuals or groups

• generate reports that can be used to plan user training programs based on equipment failure trends in certain departments or health facilities

• host libraries of regulatory requirements and safety information;

• generate the appropriate documentation for accreditation by regulatory and standard organizations

• generate reports to assist in the monitoring and improvement of the productivity, effectiveness and performance of health-care technology management.[20]

3.5.1. CMMS Core Modules:

A module is a collection of tables and data screens. The inventory module, for example, is made up of the 'equipment type' table, the 'manufacturer information' table and the 'equipment location' table.

The following sections describe the basic modules of a CMMS package.

3.5.1.1 Equipment inventory module:

The inventory module is the core of any CMMS and the first to be constructed. When new equipment is added to the inventory, the equipment is registered within the CMMS database through a data entry screen.

It is common practice to use stored default values to build inventory records for new equipment, as it reduces entry time and avoids human error.

Similarly, the other areas illustrate default values associated with the equipment model, location of medical equipment and inventory number, respectively. This allows modules to be built with maximum efficiency and maintains data integrity [21].

3.5.1.2. Spare parts inventory and management module:

The spare parts management module is an extension of the inventory module that tracks the spare parts related to equipment and helps to maintain stock levels.

Stocked parts include those that are common to a number of different pieces of equipment such as fuses, wires, batteries and basic electronic components, and those parts that are more specific to a particular model such as circuit boards, power supplies, X-ray tubes and ultrasound probes.

Some CMMS packages provide a fully automated operation that includes all phases of spare parts management from procurement to delivery, acceptance testing and use.

3.5.1.3 Maintenance module:

The maintenance module assists the user of the CMMS program to effectively manage their maintenance schedule.

The CMMS can be used for both planned preventive maintenance and corrective maintenance.

- **Planned preventive maintenance:**

With the appropriate inputs, the computerized system can calculate when a piece of equipment will require maintenance and advise which parts might need to be ordered and when. The package can also monitor the maintenance process and log when it has been completed.

- **Corrective maintenance:**

When an equipment user reports a problem with a piece of equipment, the clinical engineering department can log the fault in the CMMS system.

The program will automatically generate a work order and allow the manager of the system to assign an engineer to the job.

The CMMS program can provide information regarding workload, training and expertise of individual engineers to assist with this decision. If an initial evaluation of the fault identifies that a specific part is required to complete the job, the computerized system can record this and provide the appropriate ordering information about the part. When the job is complete the status of the equipment can be logged in the system.

Whether preventive or corrective, priority levels for the maintenance to be done can be assigned with reference to the equipment risk, the strategic value to the health facility, and the availability of back-up equipment. In addition, maintenance work order forms can be generated in electronic or paper format to include the relevant maintenance procedures required to complete the work order.

3.5.2. Scheduled and Non-Scheduled Work Orders:

The maintenance and inspection data are usually available in the CMMS of a hospital, stored in either scheduled or non-scheduled work orders. Scheduled work orders are used for routine tests (SPIs); however, when a device fails or has a defective part, a non-scheduled work order is requested to fix the problem.

Both scheduled and non-scheduled work orders include the basic information of a device and a test checklist designed for a particular class of device. The checklist contains qualitative and quantitative tests; technicians or clinical engineers should use this list to ensure that all necessary tests and checks are accomplished.

A work order presents all PM checks and actions, such as cleaning, lubricating or replacement of a device or its parts.

A work order is also created for an acceptance test of a newly received device.[1]

CHAPTER FOUR

METHODOLOGY

4.1 Introduction to CIPP program:

Understanding what devices are in the facility in order to provide a quality maintenance program is critical. Inventory data is used for a variety of applications including establishing a maintenance schedule, tracking medical device hazards and recalls, and deciding when to replace aging equipment.

A computerized medical equipment management system is a useful tool in keeping track of the device inventory and maintenance history.

CIPP is a program that controls the quality of medical devices that works at any health care institution. The basic elements of the program are: inspection, preventive maintenance and corrective maintenance. It provide an effective method to inspect medical devices at health care institutions by testing the devices and determining its periodicity time to recheck and retest it again, then the program provides all the necessary procedures to do the preventive maintenance to insure that the device is working efficiently and minutely until the end of its life time which means it reduce the device failure and increase its life time. Also the program provides the information about the used spare parts for the devices.

4.2. Benefits of the computerized quality control program:

(CIPP) program have other benefits such as:

- The important informationsof the device have been saved to identify it when needed: ((device name, manufacturer, and serial number, control (operation) number, device type, location)).
- The devices within the health care institutionhave been classified: ((life support equipment, medical equipment, utility equipment, general equipment))
- The devices within the health care institution have been documented, whereby saving every device's information in a file since its first enters to the program and this information includes everything related to the device ((classification, periodicity time to recheck and retest it, all preventive maintenance procedures that have been conducted and its dates, all failures and corrective maintenance procedures have been conducted, all spares parts that have been used)).
- The devices cleaning periods has been determined and saved.
- Provide an effective method for statically researches about medical devices in the health care institutions so it can easily gives the devices in a certain department, or the number of devices from the same manufacture company, or the number of devices from the same type, or the places or locations of the devices in the health care institution.

4.3. Description of the computerized quality control program:

The steps of designing the parts of the quality control program using the C# language have been described bellow in addition to explaining the program contents and how to use it to have the desired results.

4.3.1 Opening the program:

When clicking the program icon to open it, the program is opened and this window appears in **Figure 4.1:**

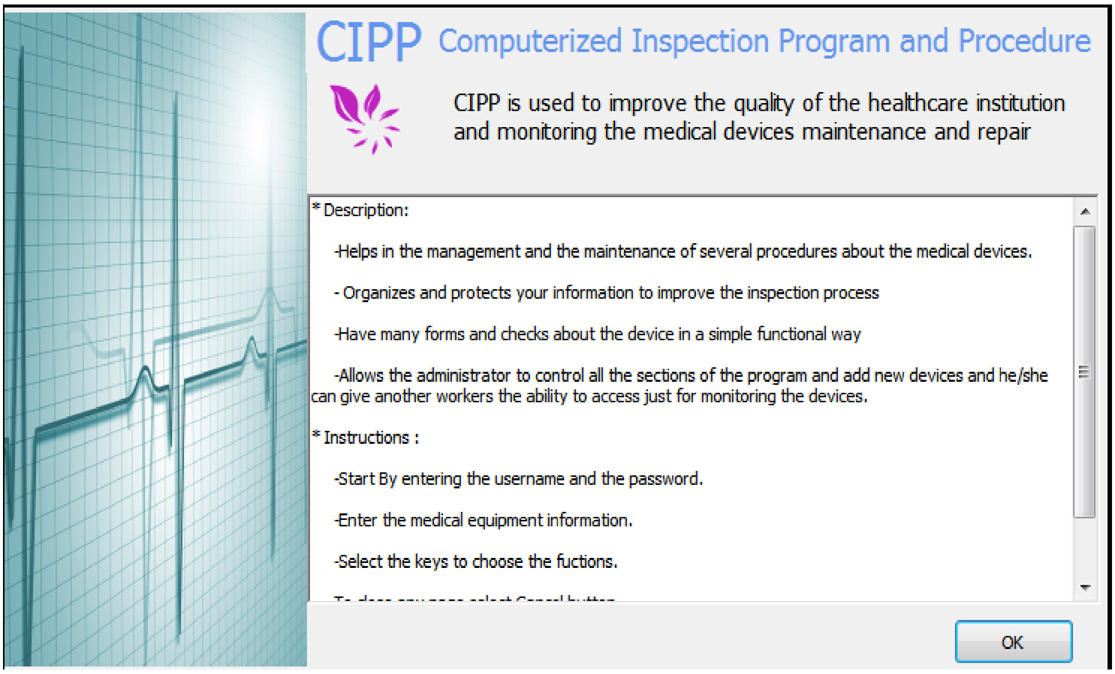


Figure 4.1: GUI of the program

Which have the program discretion and its importance in the quality control of medical devices field also it have some instruction of how the program is used correctly for users who used it for the first time. This window called graphic user interface (GUI).

4.3.2 The security part:

The security part had been designed and it appears when the program is opened, and it work on protecting the program generally and the data base and the information about the medical devices in it specially by preventing to change or delete or modify this information by non-authorized users. And to do that the validity of accessing the data in the data base and the ability to modify it or delete it or to add new devices had been made available for the administrator only who manage other users and that by giving every user a special password so those user are able to use the program only in monitoring the devices in the data base and do some available process in the program such as:

Monitoring the failures, doing the cleaning process, managing spare parts and finally making a report that evaluates the device work during the maintenance given period to the administrator.

When the administrator receives the report at the end of the inspections interval for every device he/she makes the right decision according to the information in the report which is:

1. Modify the forms if the entered data was not correct.
2. If the forms were correct the fault may be made by the users therefore they need training to have proper use for the program.
3. The device life time may ended and need to be replaced with new device.

When the program is opened this window appeared as in **Figure 4.2:**

It has the user name and the password, then the user enter them.

Figure 4.2: Main widow

4.3.3 If the user is the administrator:

The administrator has the ability to enter all the icons in the main window that shown in **Figure 4.3:**

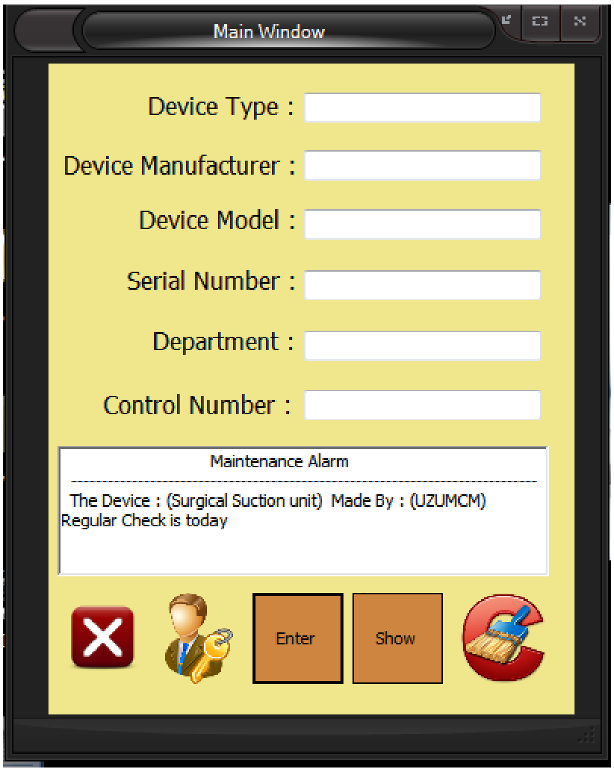


Figure 4.3: Login window

❖ The user's icon:  :

This icon authorized the administrator to manage other users, so if he clicks this icon the user's window will appear as in **Figure 4.4:**

Figure 4.4: Users' window

Where the admin can add or delete users or change in the users data and can change his name and password as in **Figure 4.5:** to add, **Figure 4.6:** to show, **Figure 4.7:** to delete:

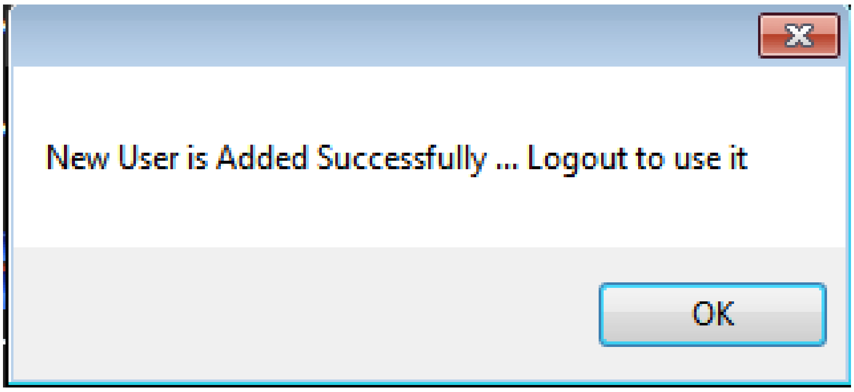


Figure 4.5: Adding new user's window

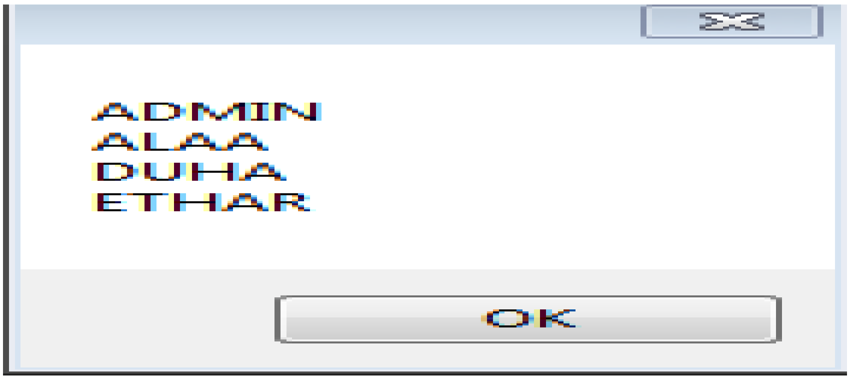


Figure 4.6: Showing user's window

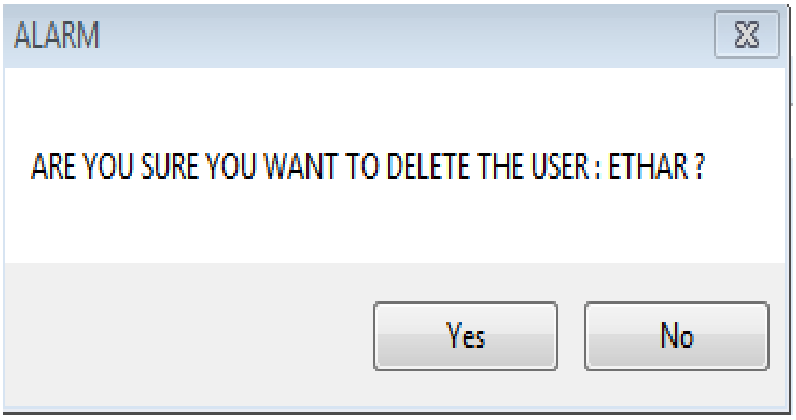


Figure 4.7: Deleting user's window

❖ Cleaning program icon: 

If the administrator clicks this icon the he will check the cleaning program so he will know devices that need to be cleaned in this day as in the next windowthat appears in **Figure 4.8:**

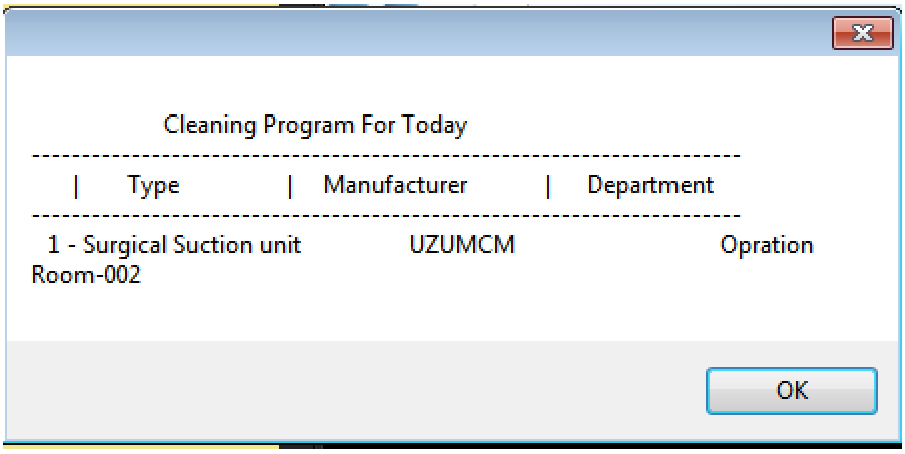
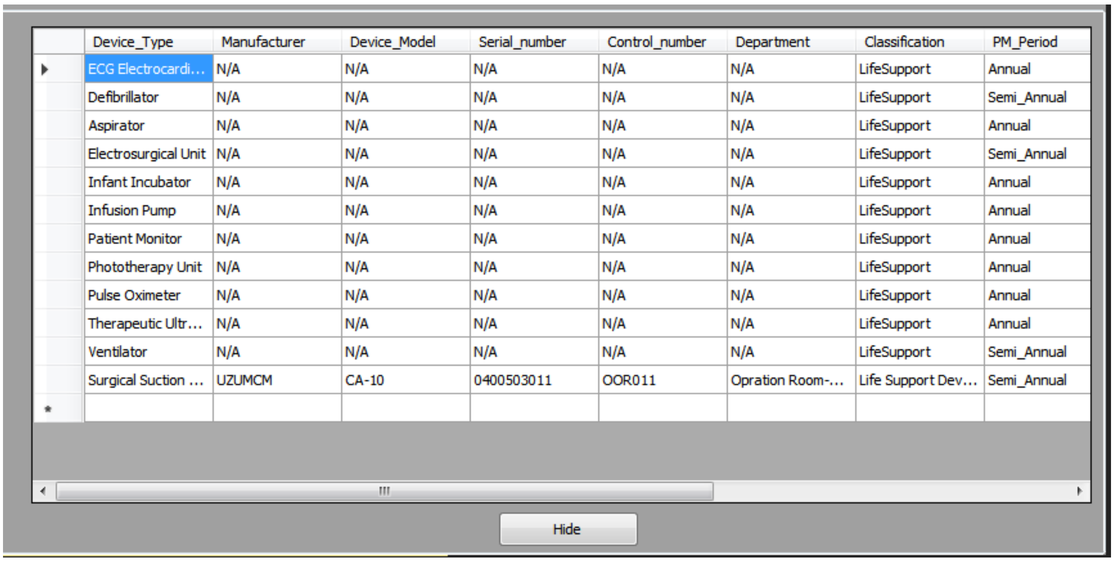


Figure 4.8: Cleaning program window

❖ The show icon:

By this icon the administrator can enter to the data base of the program and show on all the data saved for the devices which are: devices names, models, manufacturers, locations, spares parts, failures, the PM and CM procedures that had been conducted and who did it and when, digital data (SN, CN), so if he clicks this icon the data base window will appear as in **Figure 4.9:**



	Device_Type	Manufacturer	Device_Model	Serial_number	Control_number	Department	Classification	PM_Period
▸	ECG Electrocardi...	N/A	N/A	N/A	N/A	N/A	LifeSupport	Annual
	Defibrillator	N/A	N/A	N/A	N/A	N/A	LifeSupport	Semi_Annual
	Aspirator	N/A	N/A	N/A	N/A	N/A	LifeSupport	Annual
	Electrosurgical Unit	N/A	N/A	N/A	N/A	N/A	LifeSupport	Semi_Annual
	Infant Incubator	N/A	N/A	N/A	N/A	N/A	LifeSupport	Annual
	Infusion Pump	N/A	N/A	N/A	N/A	N/A	LifeSupport	Annual
	Patient Monitor	N/A	N/A	N/A	N/A	N/A	LifeSupport	Annual
	Phototherapy Unit	N/A	N/A	N/A	N/A	N/A	LifeSupport	Annual
	Pulse Oximeter	N/A	N/A	N/A	N/A	N/A	LifeSupport	Annual
	Therapeutic Ultr...	N/A	N/A	N/A	N/A	N/A	LifeSupport	Annual
	Ventilator	N/A	N/A	N/A	N/A	N/A	LifeSupport	Semi_Annual
	Surgical Suction ...	UZUMCM	CA-10	0400503011	OOR011	Opration Room-...	Life Support Dev...	Semi_Annual
*								

Figure 4.9: Data base showing window

- ❖ The exit icon:

If the administrator clicks this icon the he will exit from the program and close it as in **Figure 4.10:**

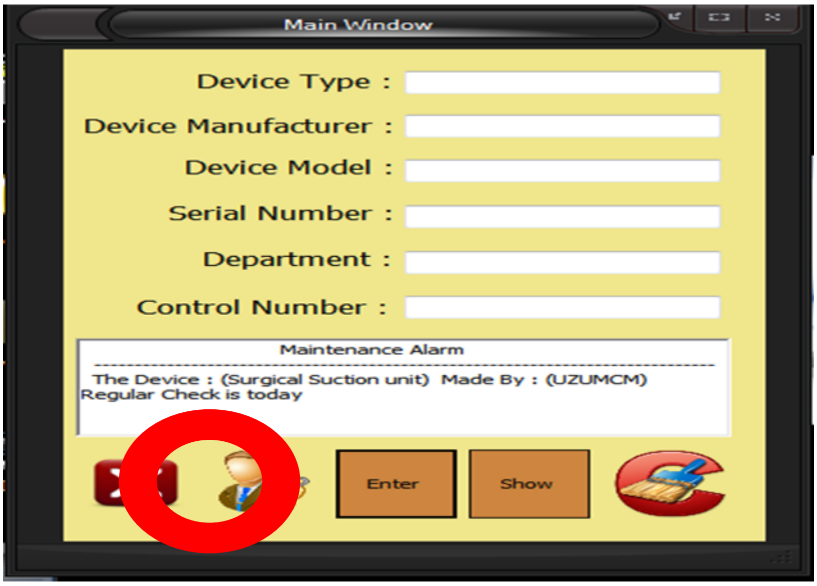


Figure 4.10: Exit icon window

❖ The enter icon:

After the administrator entered the device data and clicked on entericon, if it is the first time to enter this device to the program then the program asks if the administrator want to save the device or not as in this window that appears in **Figure 4.11**.

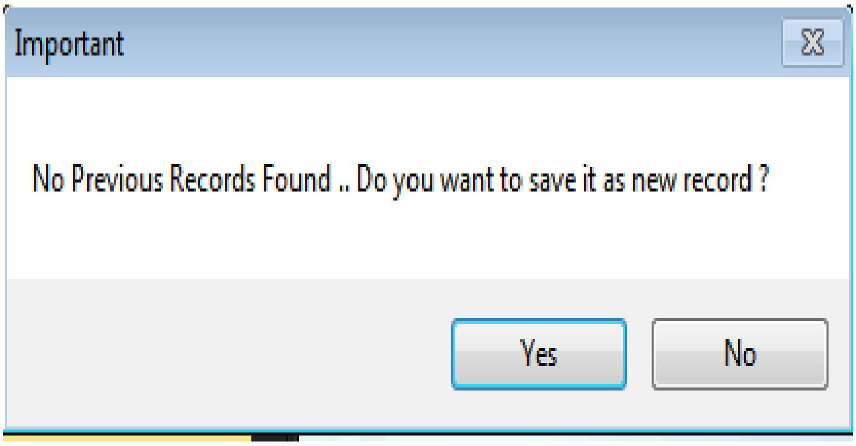


Figure 4.11: First enter to the device window

4.3.3.1 The device enters the program to the first time:

After the administrator assured the program he wants to save it he will go directly to the forms, so he will go to the next steps by filling all the forms to specify the device information's and then save it in the data base.

1. The first form (inclusion assessment form):

The intent is to capture all powered devices that by function, physical risk, maintenance requirements, or a history of incidents or safety problems should be managed as a part of the medical equipment management system. Some devices have a borderline inclusion between medical equipment and utilities, so tests for inclusion in the utilities management program are included.[2]

This form provides some questions and the administrator should answer them to get the device classification.

The process to determine what devices will be managed as part of the equipment management system is crucial to the success of the system. All devices must be evaluated. Three major classifications of devices have been used: clinical, utilities, and general. Within the clinical classification, two subgroups will be identified: life support and non-life-support.

Clinical equipment is any equipment used for treatment, monitoring, or diagnosis of patients.

Life support equipment is clinical equipment that takes over a function of the body and will cause immediate, within minutes, death if removed. All major device classes should be assessed for inclusion based on function, risk, maintenance requirements, historical incidents, and regulations and each device type should be evaluated.

Evaluations should be performed on new device types as they arrive at the hospital. All equipment used in the hospital should be evaluated regardless of ownership. Most commonly, devices will fall into the clinical classification Device inclusion must be performed and documented prior to any equipment use preferably during the technology planning stage prior to arrival at the facility.

The inclusion assessment form appears in **Figure 4.12**and **Figure 4.13**

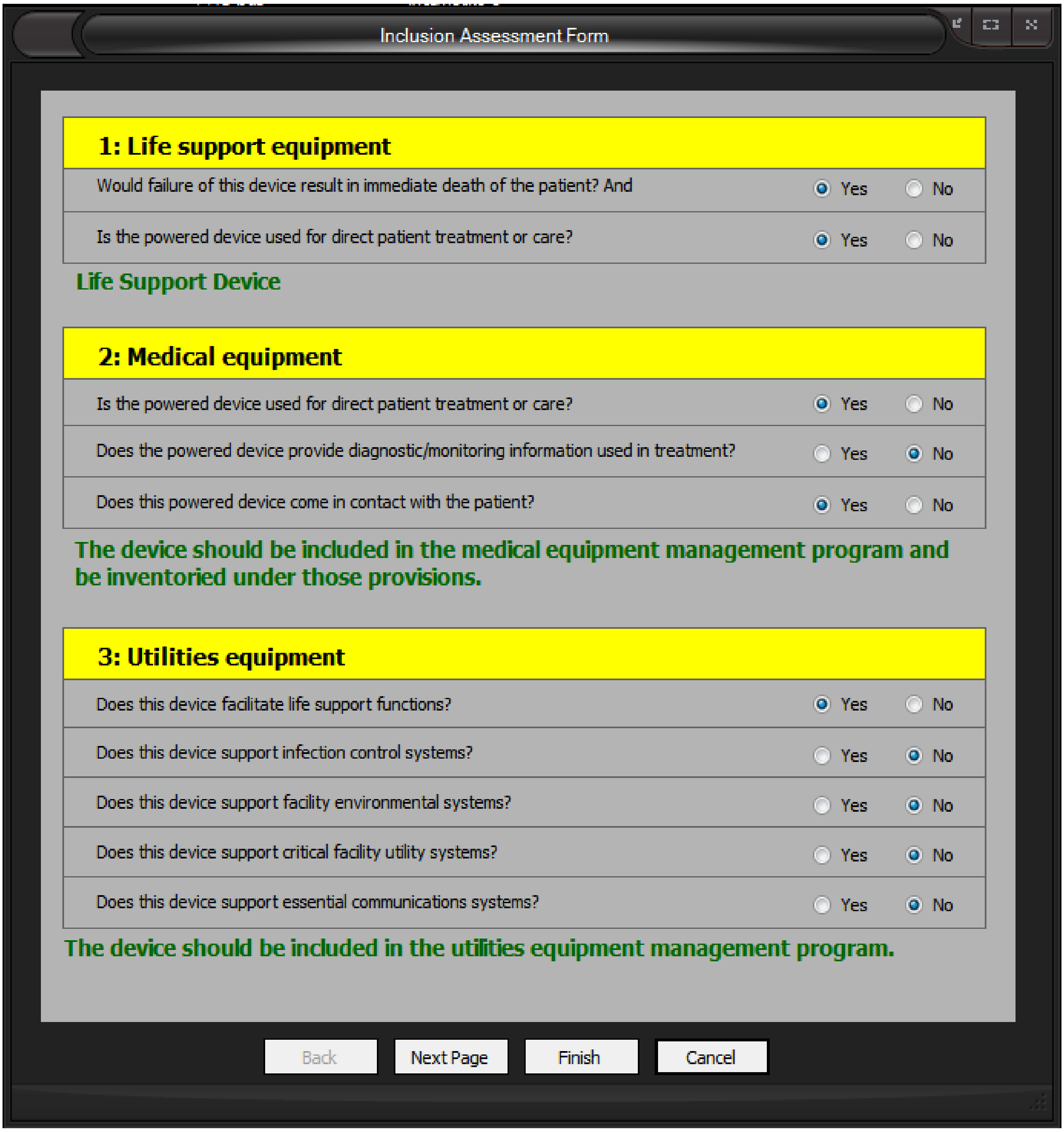


Figure 4.12: Inclusion assessment form 1

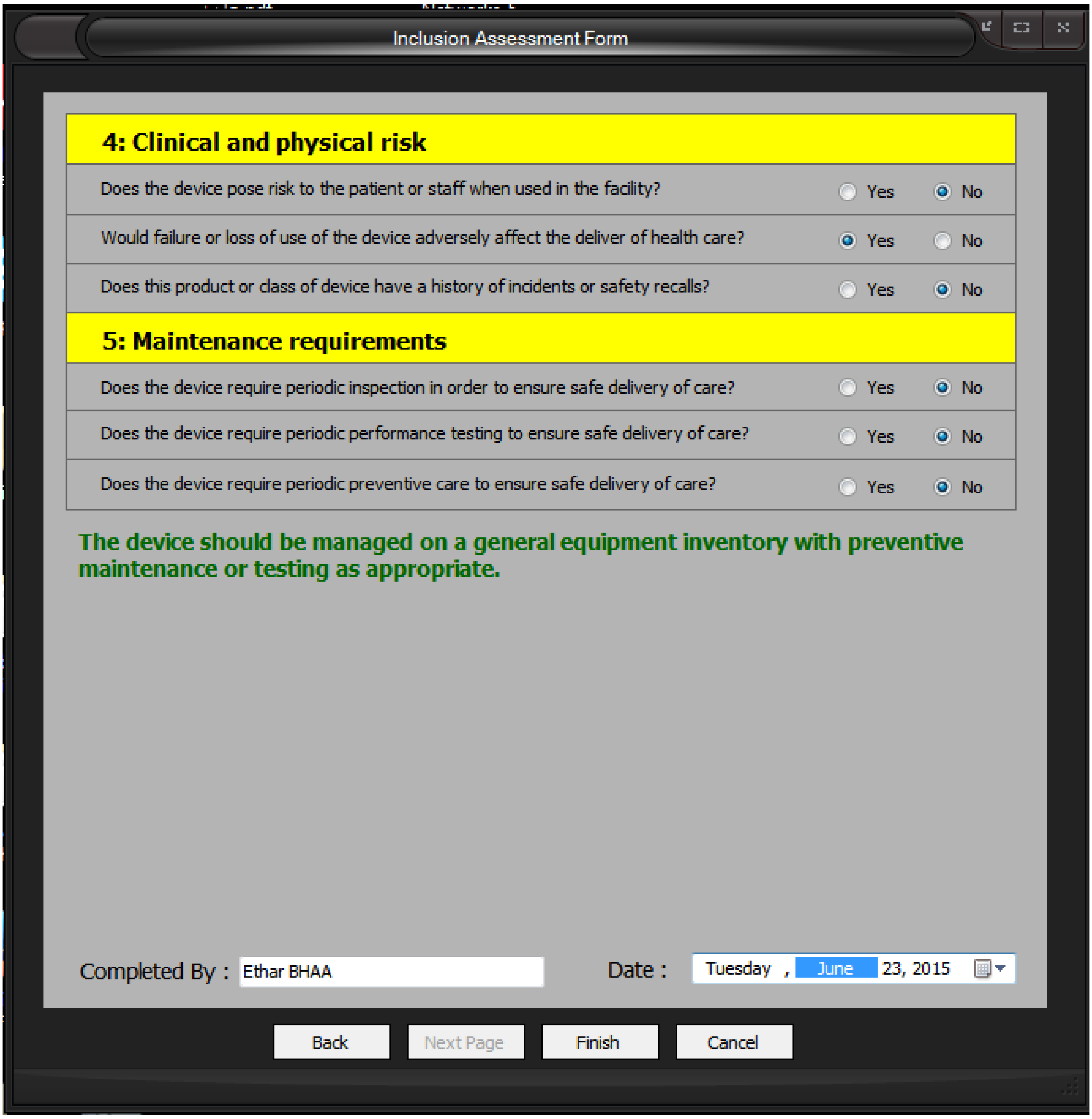


Figure 4.13: Inclusion assessment form 2

2. The second form (maintenance strategy form):

Most device types have been evaluated and classified for test frequency already.

For new device types, use the scoring system to evaluate the frequency of testing.[2]

A risk assessment model has been presented in this form, which can be used to prioritize medical devices and establish guidelines for selecting appropriate maintenance strategies.

The risk assessment should be done for each new device type during the incoming inspection when the device is added to the inventory. The device will then have a testing frequency assigned. After this is done, the maintenance history of the device should be monitored in order to evaluate the effectiveness of the maintenance program.

The risk criterion is divided into five categories: clinical function, physical risk, problem avoidance probability, incident history, and regulatory or manufacturer requirements. Devices are given a score for each of these categories.

As has been noted, the proposed model prioritizes devices according to their criticality. The normalized score value indicates the relative criticality of a device compared to other devices. Given such a model, hospitals could focus their maintenance efforts on more critical devices. Devices with lower criticality scores could be discarded from a maintenance management program, while devices with high score values could be monitored and supervised.

Normalized scores can be used for prioritizing or ranking of devices. The normalized scores depend on the total number of devices involved in the model.

In this model, devices can have a total score between (5, 18). Score 18 is for a device which gets the highest intensity when assessed against every single criterion, and 5 is obtained when the device gets the lowest intensity from all criteria. Therefore, the score in the proposed model is always between 5 and 18.

The scores for each category are added up and a total score is given for each device type. Maintenance strategies are determined based on the total score. A combined score of 13 or more is justification for semiannual testing, a score of 9-12 is justification for annual testing, and a score of 8 or less is justification for less the annual testing, either bi-annual or no scheduled testing, depending on clinical application. The result is a more cost-effective test program that will result in improved patient care through less equipment downtime for direct patient care activities

The risks identified are used to assist in determining the strategies for maintenance, testing, and inspection of medical equipment. In addition the identified risks are used to guide the development of training and education programs for staff that use or maintain equipment. All medical equipment is screened at the time of delivery and appropriate training and testing of new equipment takes place prior to use on patients.

This software developed C# respect all these conditions above.

By clicking finish in the previous form, the program will move directly to this form which appears as in **Figure 4.14**and **Figure 4.15**

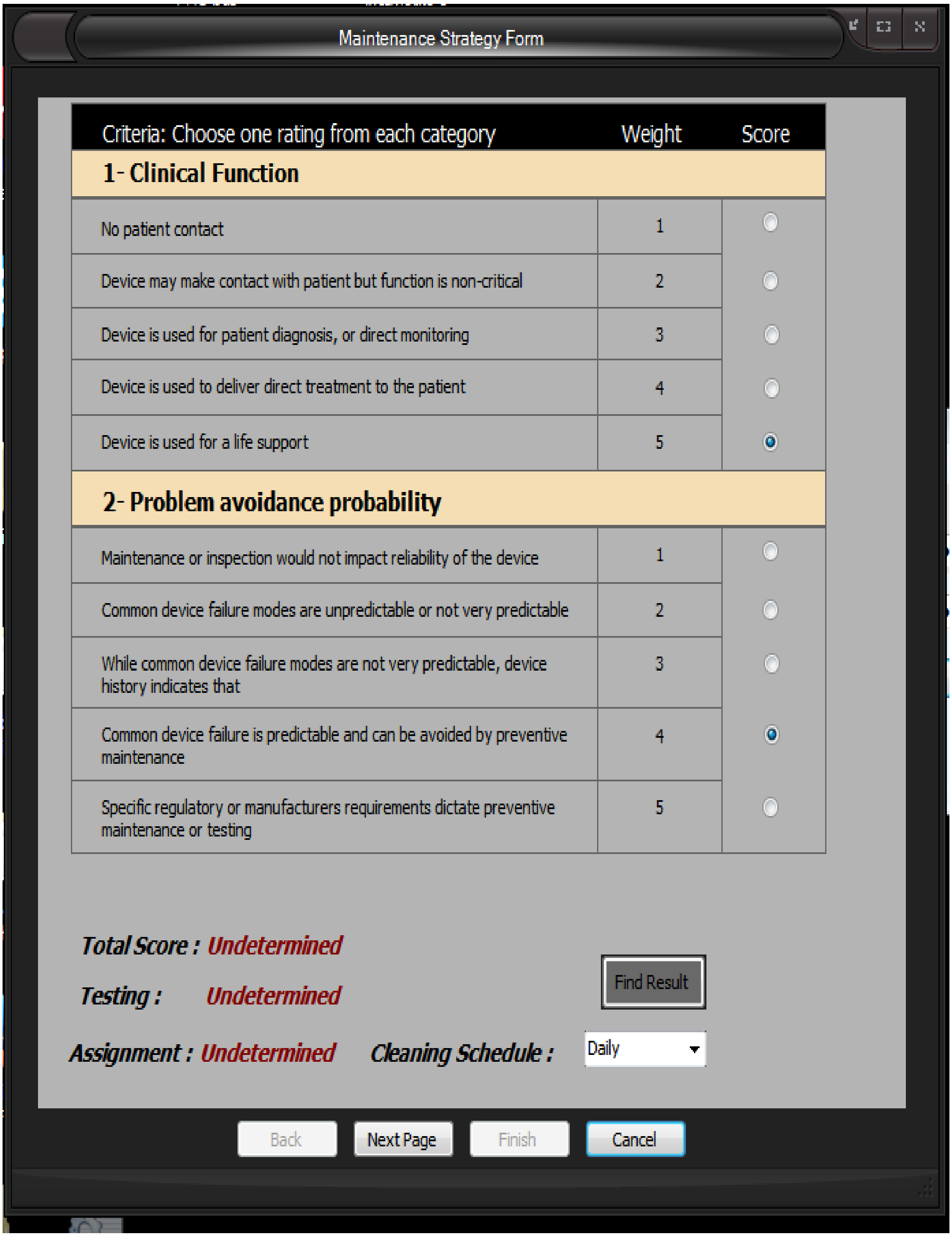


Figure 4.14: Maintenance strategy form 1 [1]

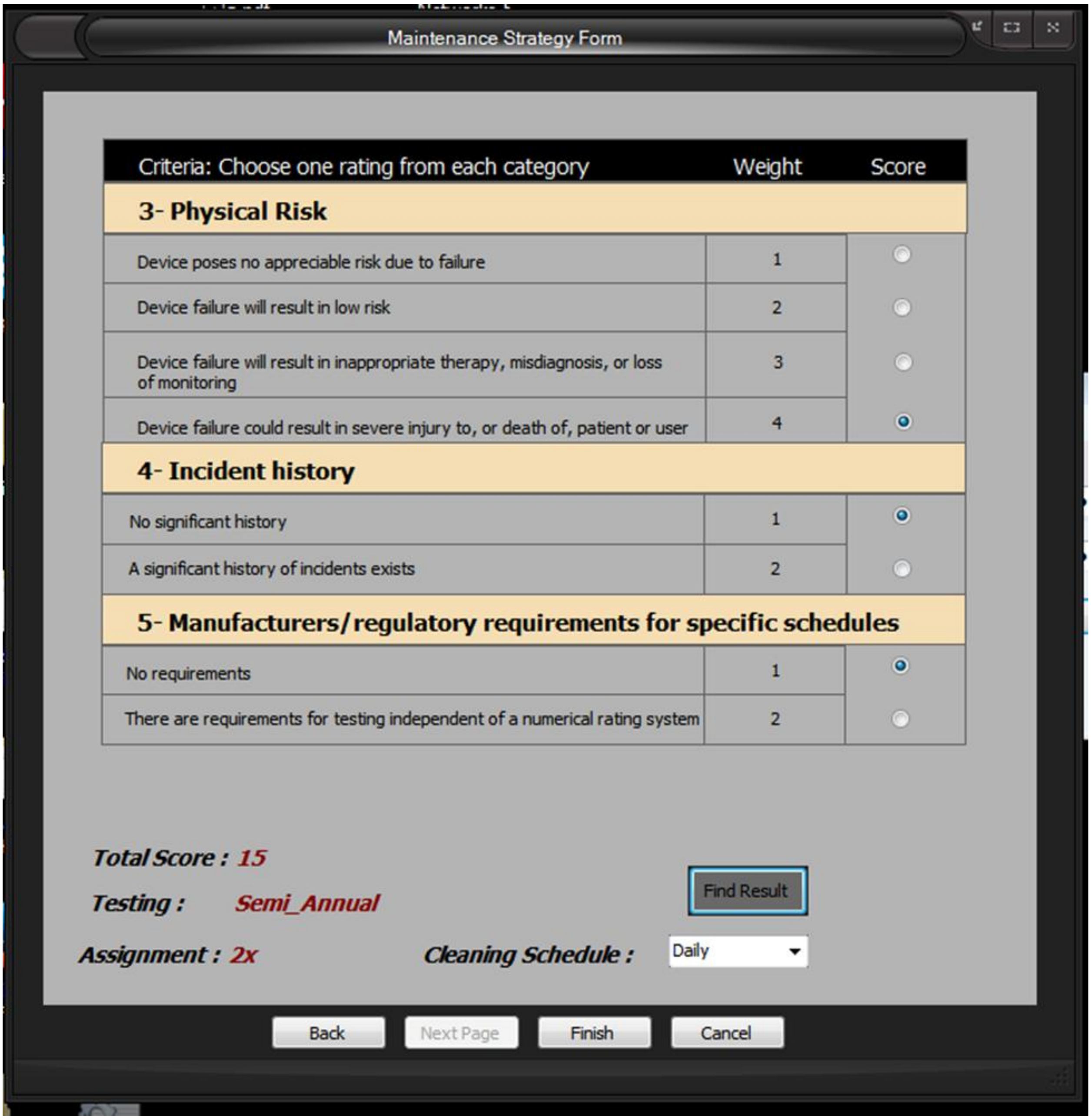


Figure 4.15: Maintenance strategy form 2 [1]

3. The third form (general procedures form):

Physical condition and electrical safety are general maintenance requirements that apply to all medical equipment. This information will appear on all checklists and should be performed during all inspections. These general maintenance tasks will not be discussed in the specific device procedures[2]

This form have the general procedures should be followed for every device to ensure some important elements to get better results from the device.

Physical condition and electrical safety are general maintenance requirements that apply to all medical equipment. This information will appear on all checklists and should be performed during all inspections. These general maintenance tasks will not be discussed in the specific device procedures.

Physical condition:

These tasks check the physical condition of the equipment. These tasks should be performed for all medical equipment.

• Device is clean and decontaminated:

• No physical damage to case, display, mounts, cart, or components.

Examine the exterior for cracks and chips.

Check that shelves and brackets are secure.

Check the condition of castors and ensure they turn and swivel as appropriate. Check the operation of the brakes.

• Switches and controls operable and correctly aligned.

• Display intensity adequate for daytime use.

• Control numbers, labeling, and warnings present and legible.

• Inlets and hoses.

• Power cord, patient and accessory cables, charger.

• Filters and vents clean.

Electrical safety:

These tasks check the electrical safety of the equipment and are important to prevent a shock to the patient. Electrical safety should be checked for all medical equipment.

• Device specific tasks

Preventive maintenance and performance inspection include maintenance tasks and testing criteria that are specific for each device type. These tasks should be performed in addition to the general physical and electrical safety tests.

Preventive maintenance:

Complete model-specific preventive maintenance:

Refer to the monitor's service manual for preventive maintenance tasks specific to the device. Complete the preventive maintenance per manufacturer's procedure.

Performance inspection:

Complete model-specific performance testing: Refer to the service manual for performance inspection tasks specific to the device.

Complete the performance inspection per manufacturer's procedure and finally returning the device to service.

This form appears as in **Figure 4.16** and **Figure 4.17.**

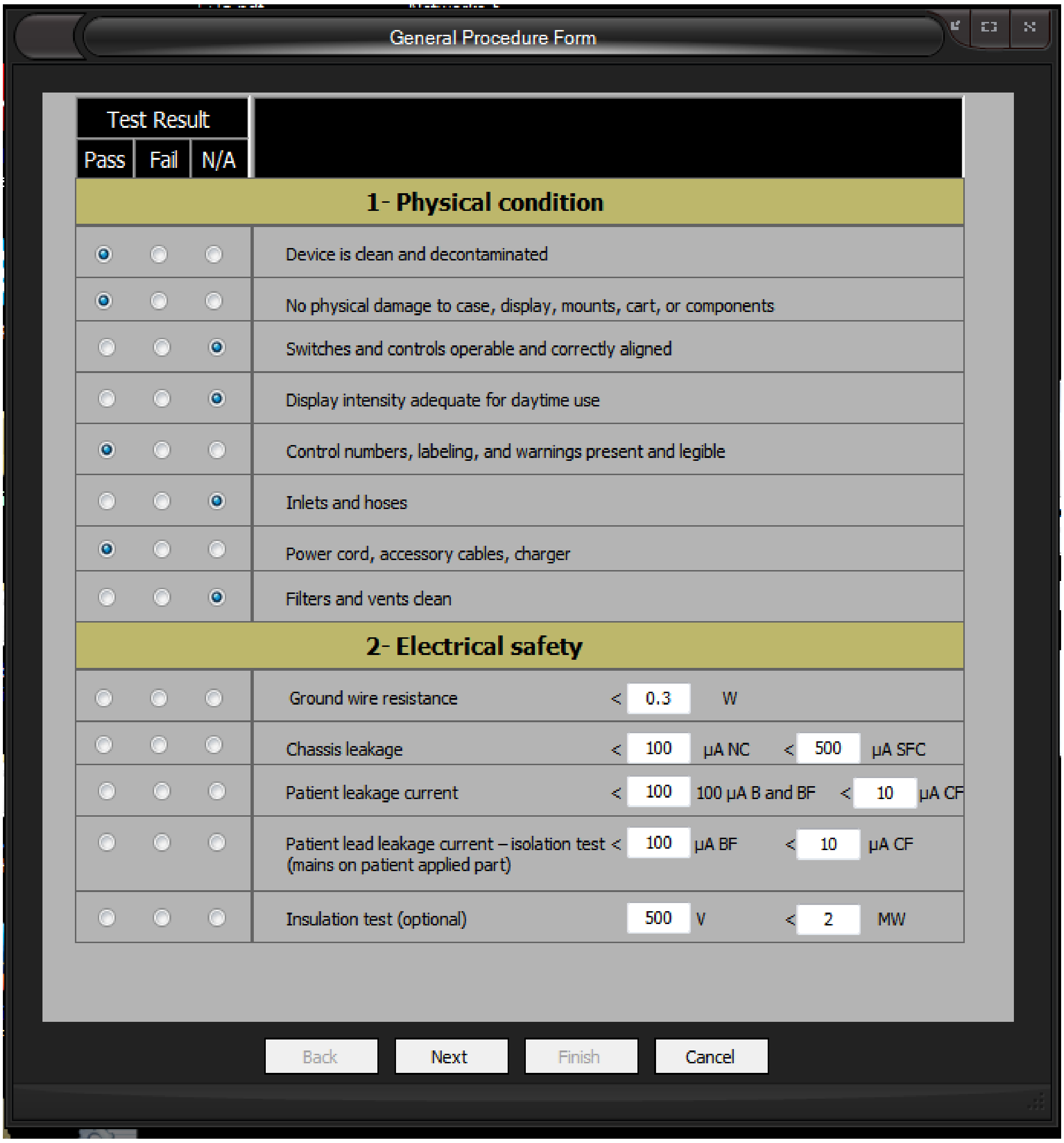


Figure 4.16: General procedures form 1 [1]

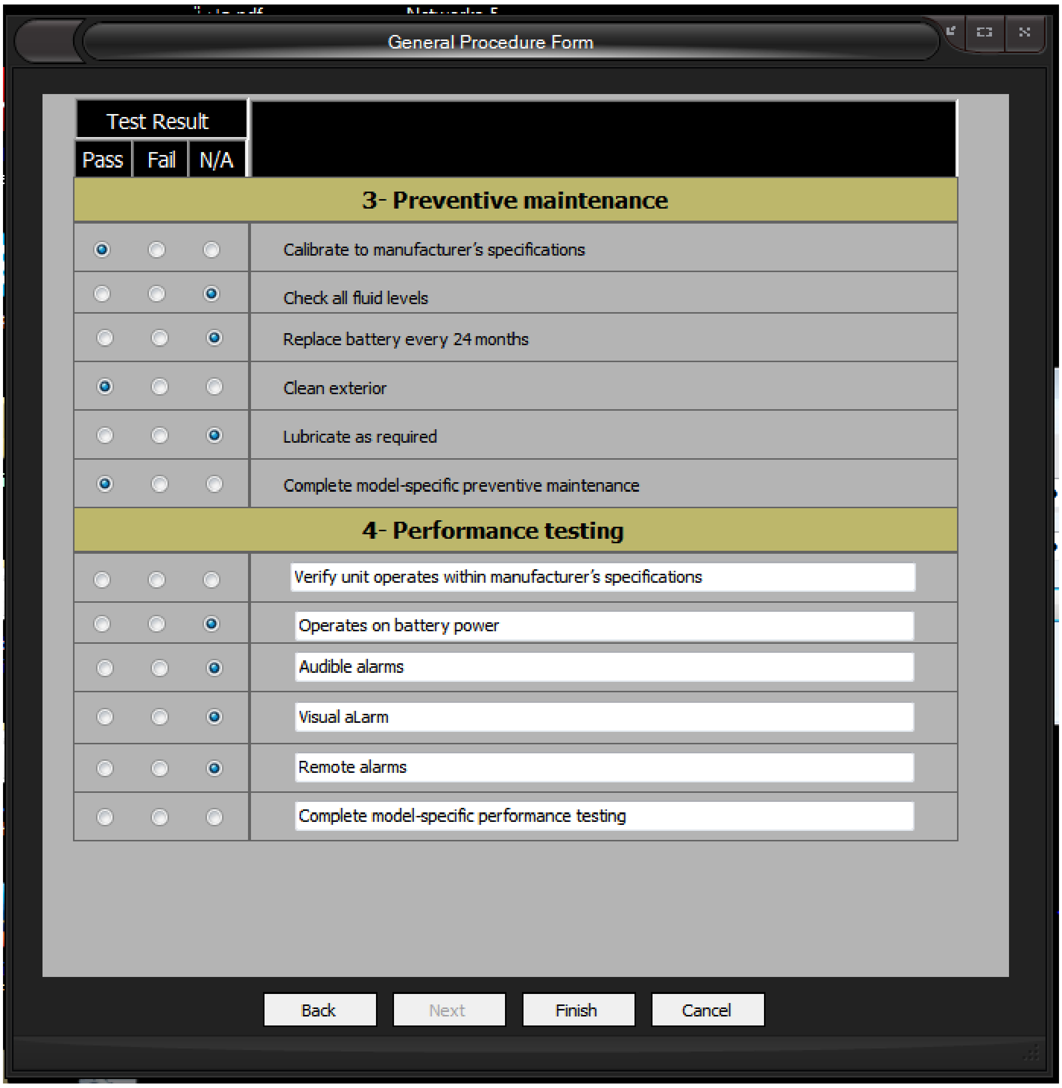


Figure 4.17: General procedures form 2 [1]

After finishing and filling all the forms the program asks if you want to save this device with all the entered information as in **Figure 4.18:**

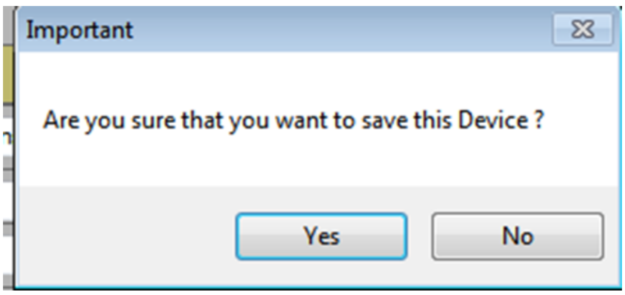


Figure 4.18: Saving devices window

Then directly the program will display a window with a summary for all the device information as in **Figure 4.19:**

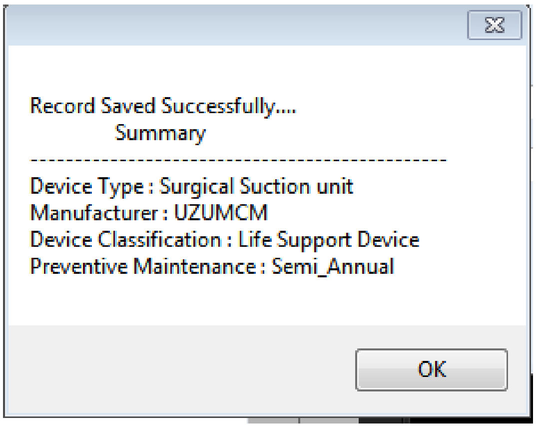


Figure 4.19: Summary window

4.3.3.2 The device was already saved in the program:

If the device was already saved in the program after entering the data and clicking enter this window appears as in **Figure 4.20**:

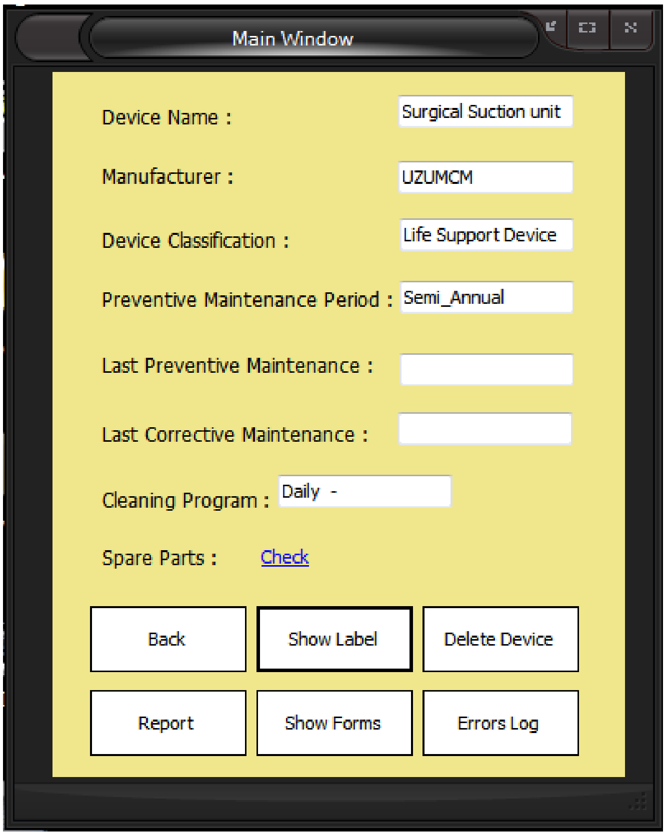


Figure 4.20: Saved device window

This window provides the classification of the device and the preventive maintenance period as the results of its form, last preventive maintenance, last corrective maintenance and the cleaning program. In this window there are some options the administrator can use them, these options are:

- Back

By clicking (Back) the administrator can get back to the main window.

- Show label

If the administrator clicks (show label) the program will display the device's label where this label contains the maintenance strategy of the device, the name of the operator who tested it and the date of the test as in **Figure 4.21:**

And there is an ability to print the label to use it on the device.

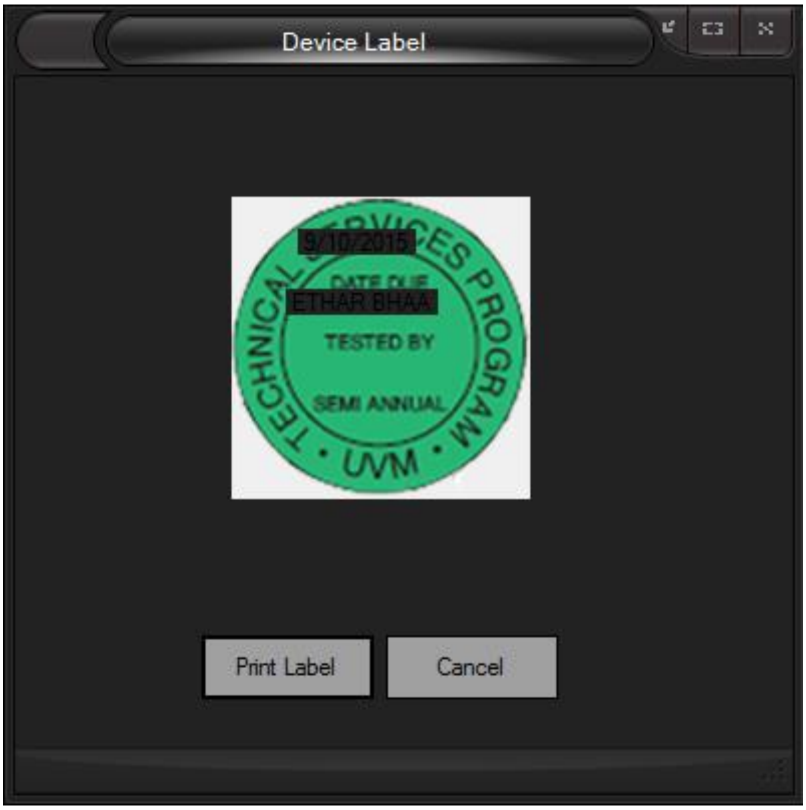


Figure 4.21: Label window

- Delete device

By clicking (delete device) the administrator can delete the device and the program will display this window as in **Figure 4.22:**

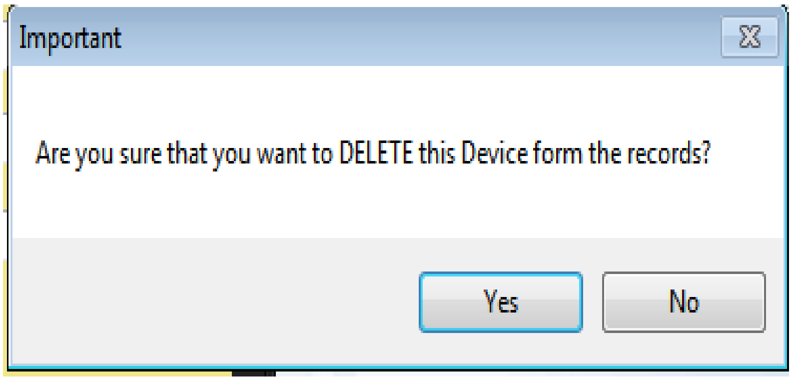


Figure 4.22: Delete device window

- Error log :

  By clicking (error log) the program opens a window that has all errors and failures happened in the device and the preventive maintenance procedures that have been conducted since its first enters into the program as in **Figure 4.23.**

  The administrator also can add corrective maintenance procedures to the history of the device by choosing the maintenance type as corrective and then the program directly enables the work order part, so when the administrator choose the error from the work order form then the program will add the code of that error to the history of the device.

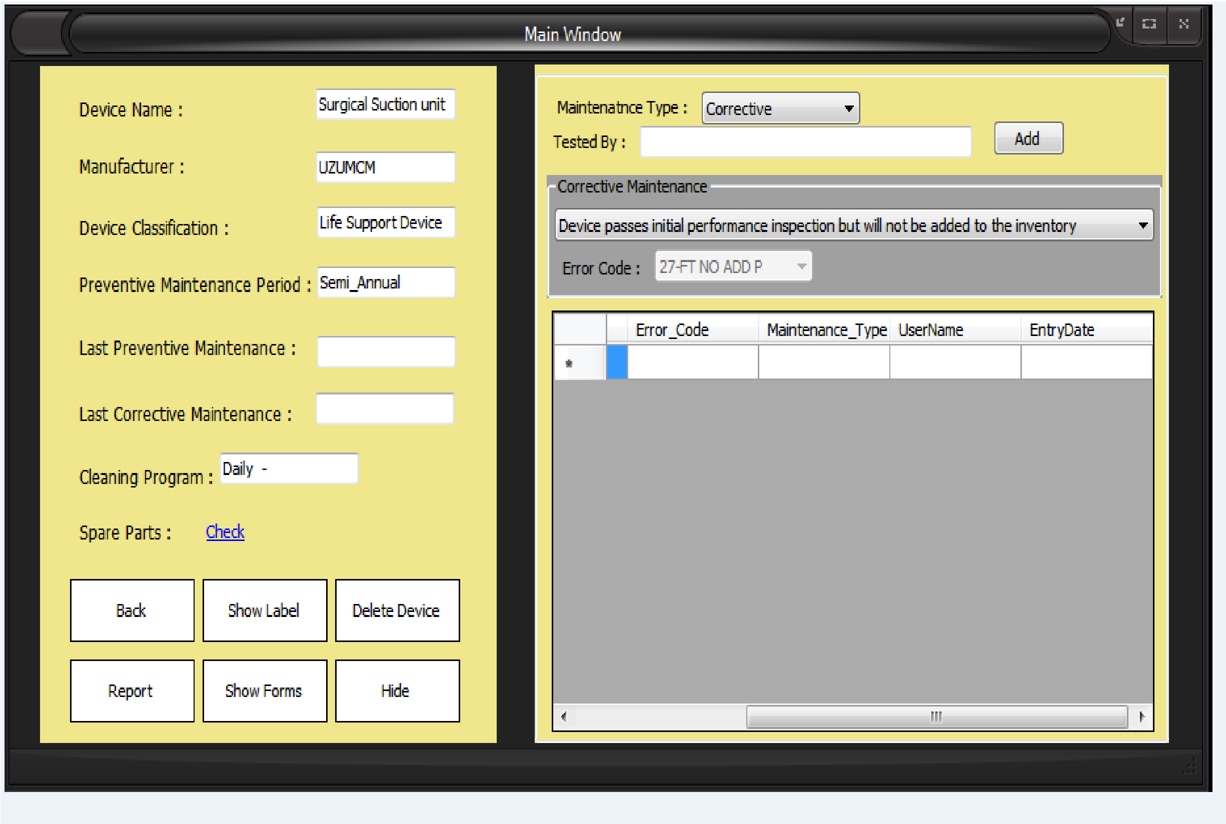


Figure 4.23: Error log window 1

The administrator can add preventive maintenance procedures to the history of the device by choosing the maintenance type as preventive and then add his/her name as in **Figure 4.24:**

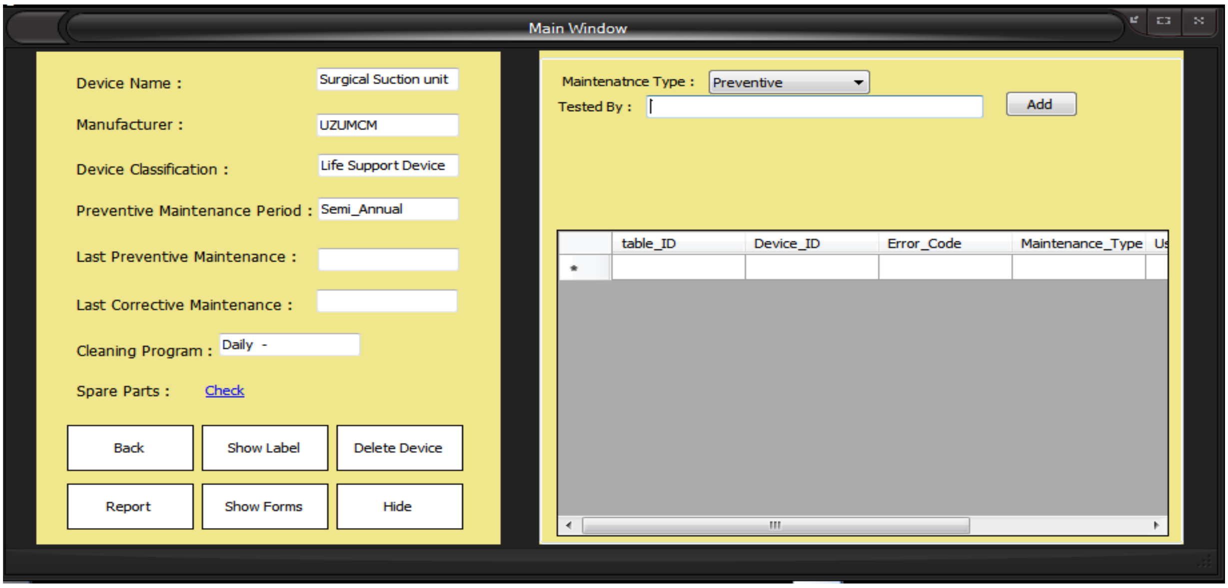


Figure 4.24: Error log window 2

- Check

By clicking (check) the administrator can open the spare parts window and show on all the spare parts that have been used with their information such as spare-ID, device –ID, spare name, spare number and spare manufacture as in the window shown in **Figure 4.25.**

In case of adding new spare or deleting it, the program will ask about the spare parts name, manufacturer and the part number.

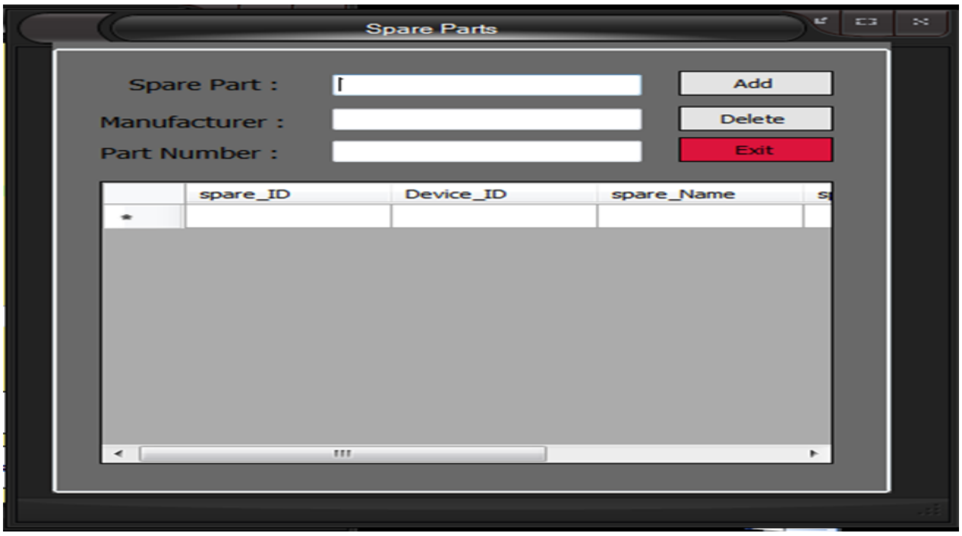


Figure 4.25: Spare parts window

- Report:

By clicking (report) the program DISPLAYs a full report describing the specific device and contains the device information, classification, inspection period, its last inspection, the next inspection date and the name of the operator who need the report as in **Figure 4.26:**

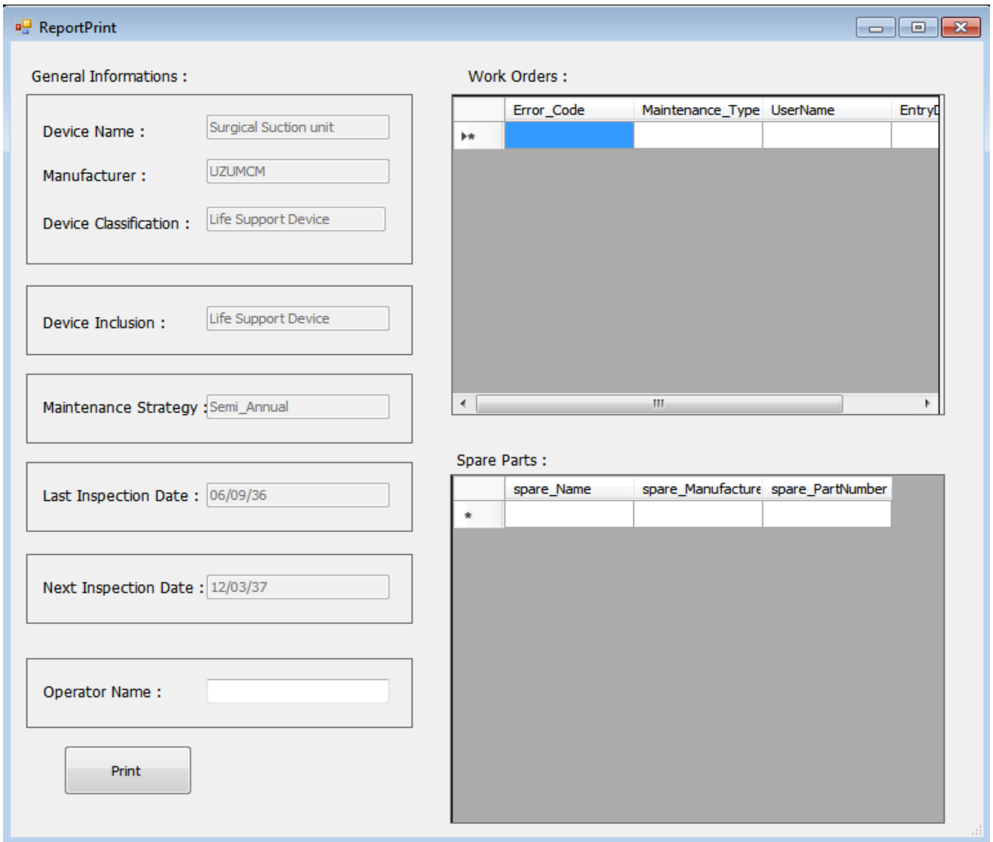


Figure 4.26: Final report window

The administrator is able to enter to the data base by the password he saved so nobody non-authorized would see it or change it. The data base has all the data about the saved devices in the program and this show in **Figure 4.27**, **Figure 4.28,** and **Figure 4.29:**

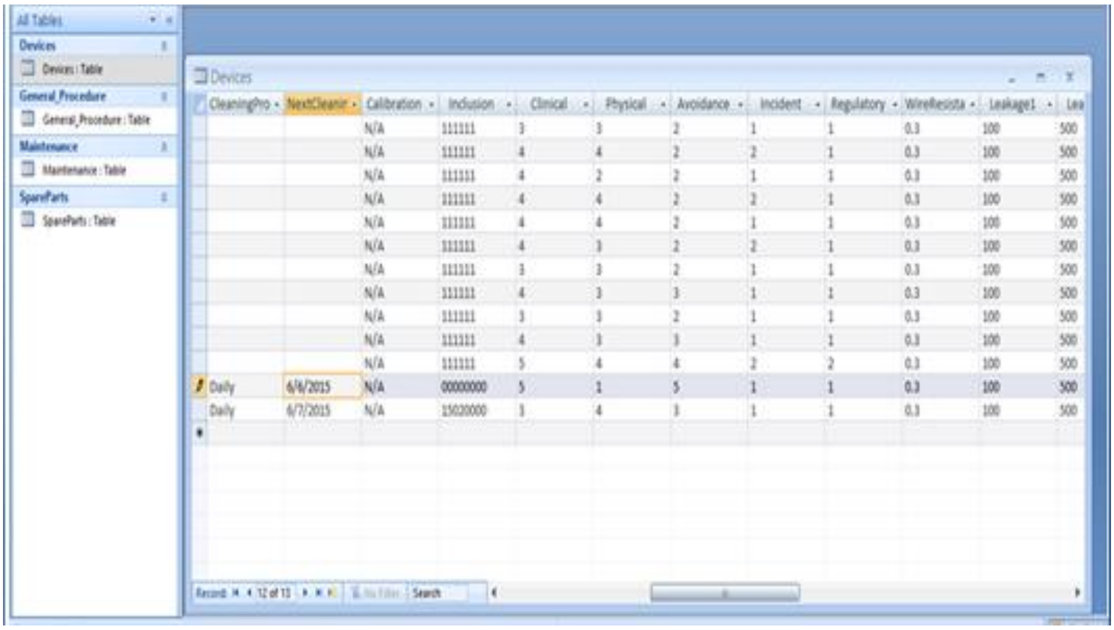


Figure 4.27: Data base window 1

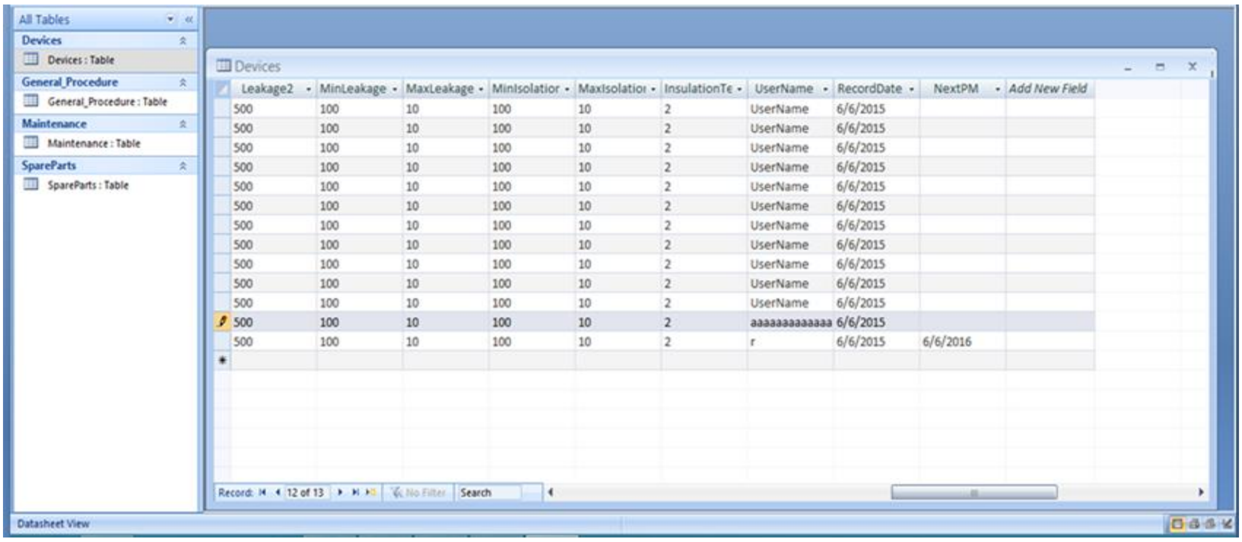


Figure 4.28: Data base window 2

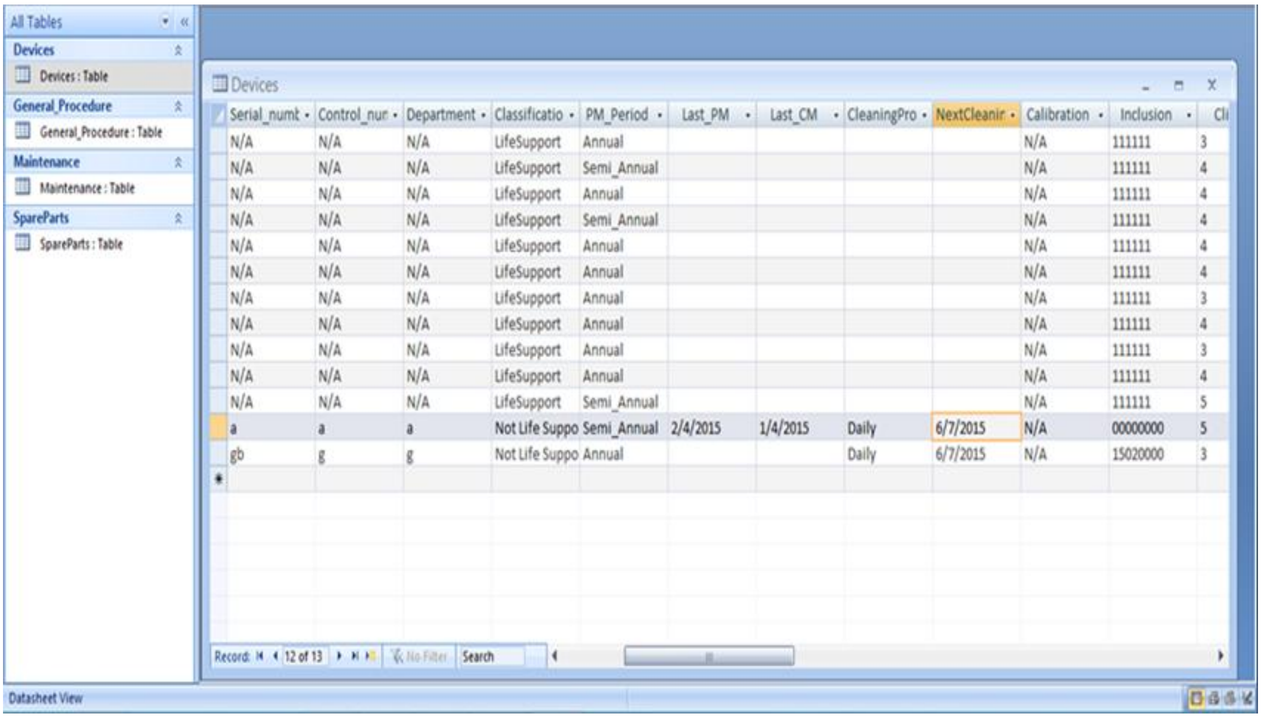


Figure 4.29: Data base window 3

4.3.4 If the user is not the administrator:

In case the user is a regular user not the administrator when he enters his name and password the main window will appear as in **Figure 4.2.**

When the user clicks the enter icon in the main window after entering the information of a new device this window will appear as in **Figure 4.30.**

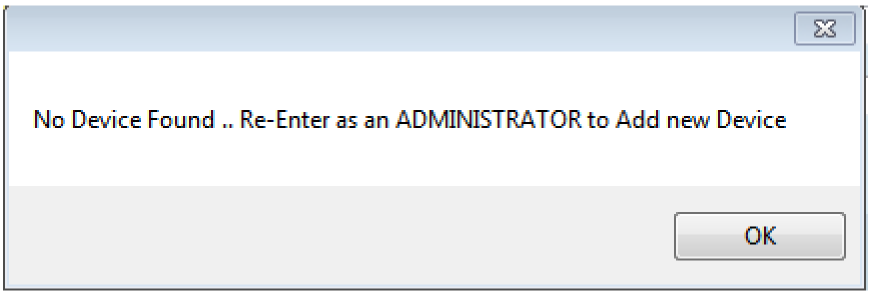


Figure 4.30: Inability to add new device

So he is not allowed to enter a new device, but if the device is already saved the widow in **Figure 4.20** will appear.

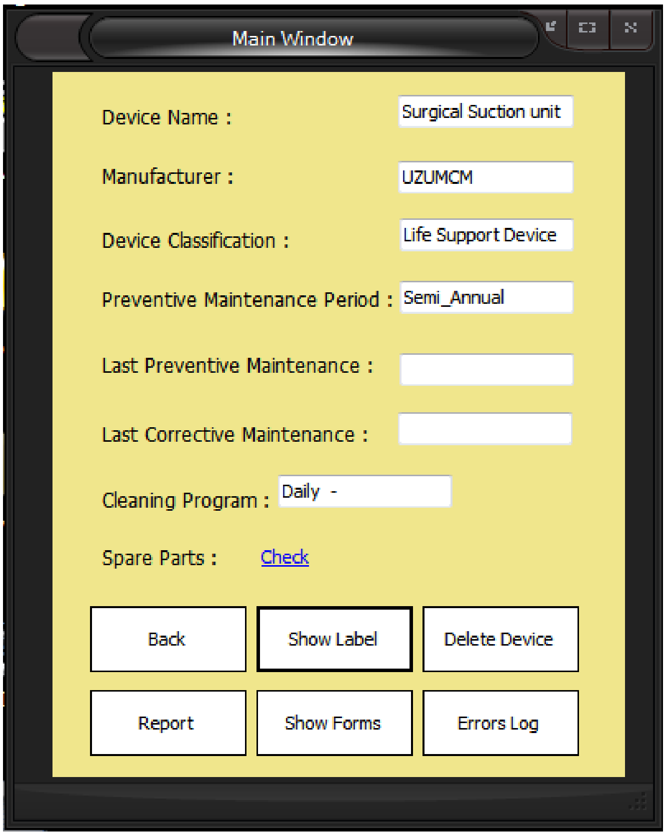


Figure 4.20: Saved device window

This user can use all the options in this window (Back, Show label, Delete Device, Show Form, Error Log and Report) as the administrator use them , so the user has the ability to access the device history and add the new preventive or corrective maintenance procedures, also he/she can manage the spare parts of the devices and so on.

But he/she is not allowed to add a new device to the data base (the program) and to enter to the data base. Else he/she can use all the program parts.

CHAPTER FIVE

RESULTS AND DISCUSSION

5.1 Results:

The program has been tested and run in four healthcare institutions they are A, B, C and D, where the inspection process was conducted on all their medical devices (here five devices were selected from each hospital as a sample to reflect the rest of the devices) and then these devices have been evaluated in terms of device classification, maintenance strategy and history of the devices and reached the following results.

- Hospital A

  Electrosurgical unit
  zentri fugen
  Anesthesia machine
  Lithotripsy
  Digital photo calorimeter

- Hospital B

  Therapeutic Ultrasound
  Electro surgical generator
  Ventilator
  Defibrillator
  Electro cardio graph

- Hospital C

  Electrosurgical
  Patient monitor

Patient Monitor

Infusion pump

X-ray conventional

- Hospital D

Infant Incubator

Hot air Oven

Operation lamp

Ventilator

Patient Monitor

- Hospital A:

Figure 5.1: Basic information of zentri fugen

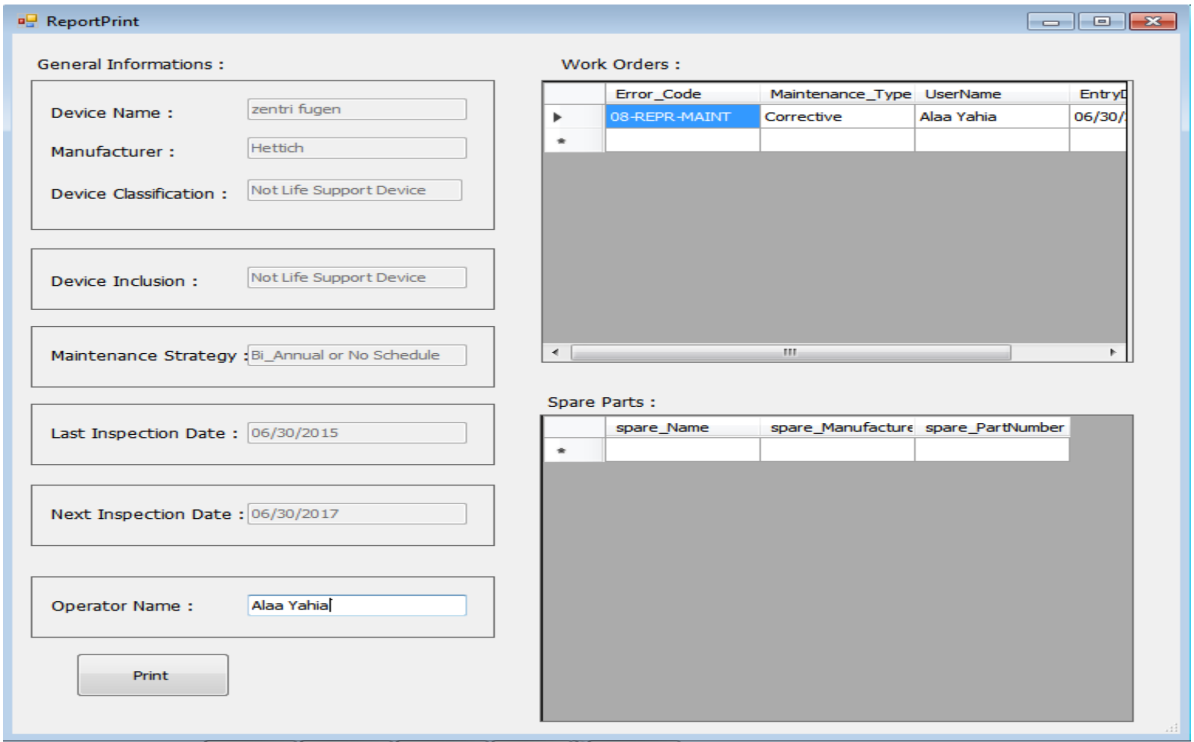


Figure 5.2: Final report of zentri fugen

Figure 5.3: Basic information of anesthesia machine

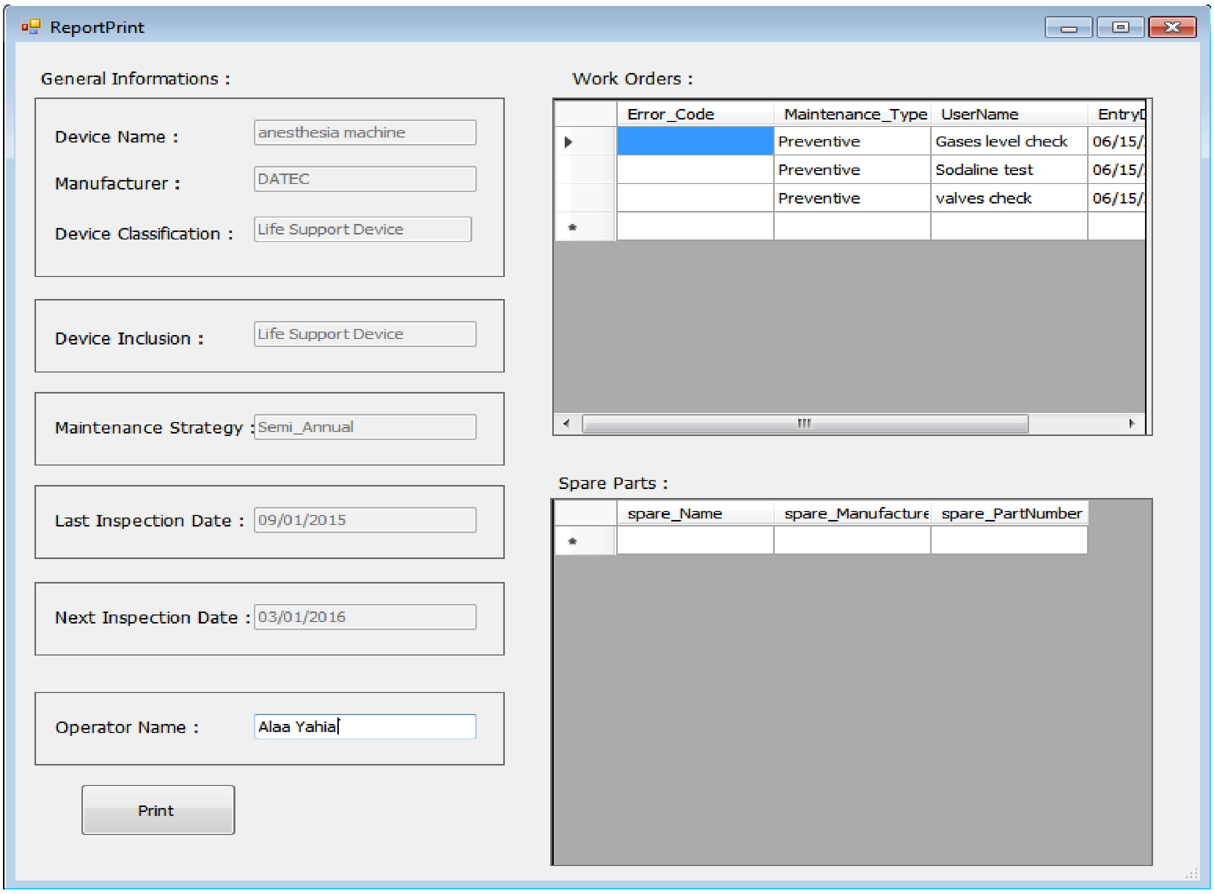


Figure 5.4: Final report of anesthesia machine

Figure 5.5: Basic information of lithotripsy

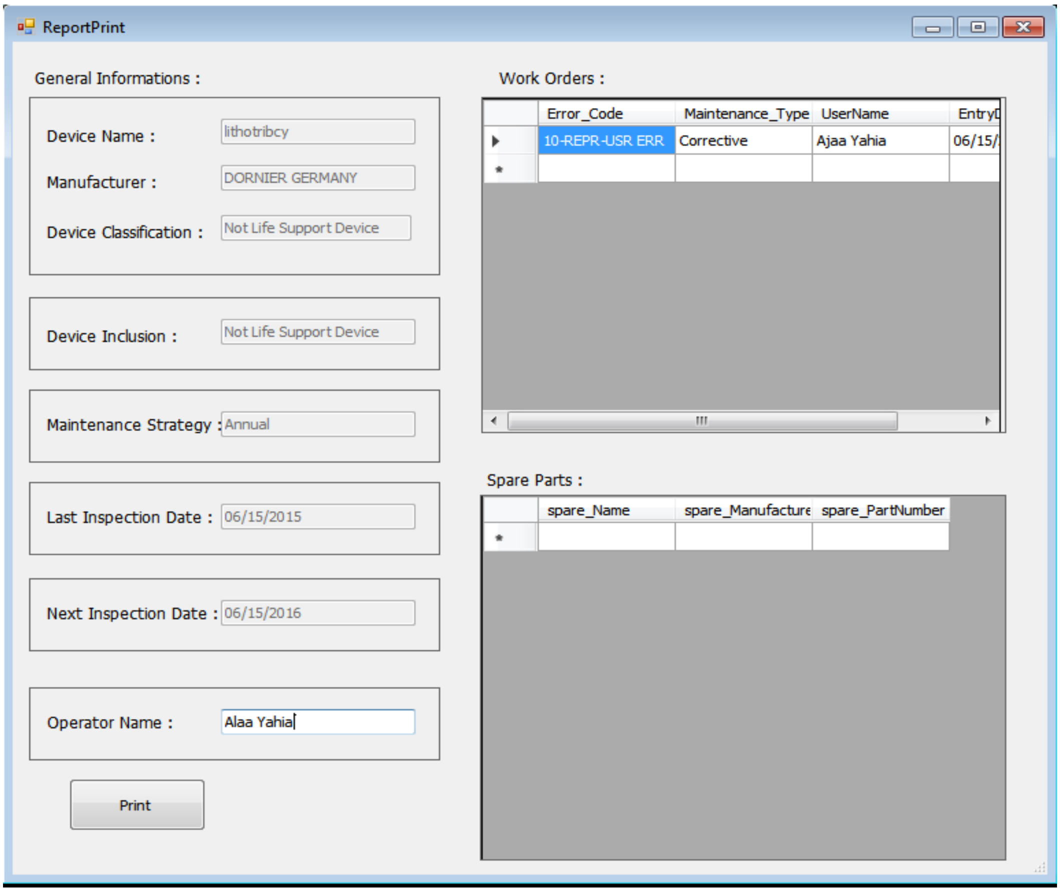


Figure 5.6: Final report of lithotripsy

Figure 5.7: Basic information of digital photo calorimeter

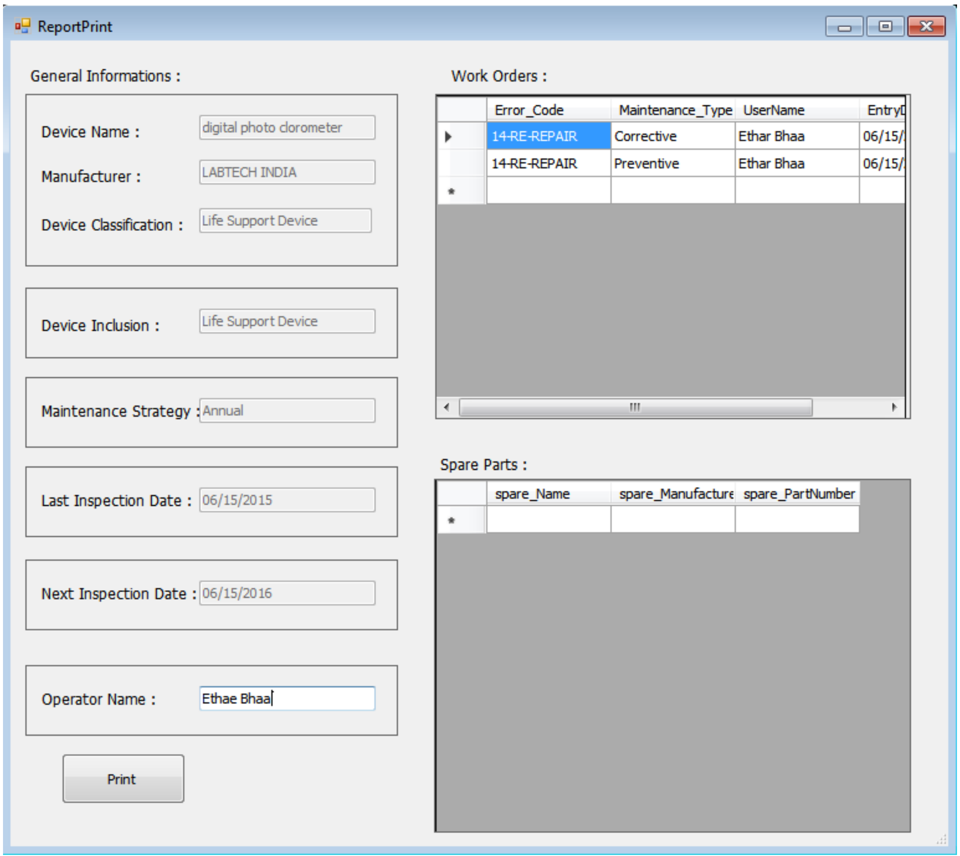


Figure 5.8: Final report of digital photo calorimeter

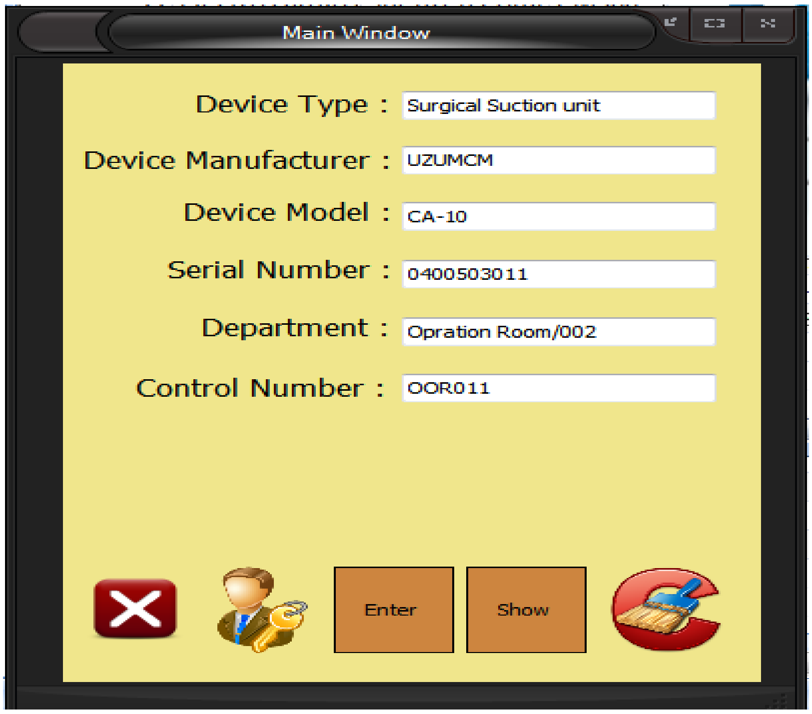


Figure 5.9: Basic information of surgical suction unit

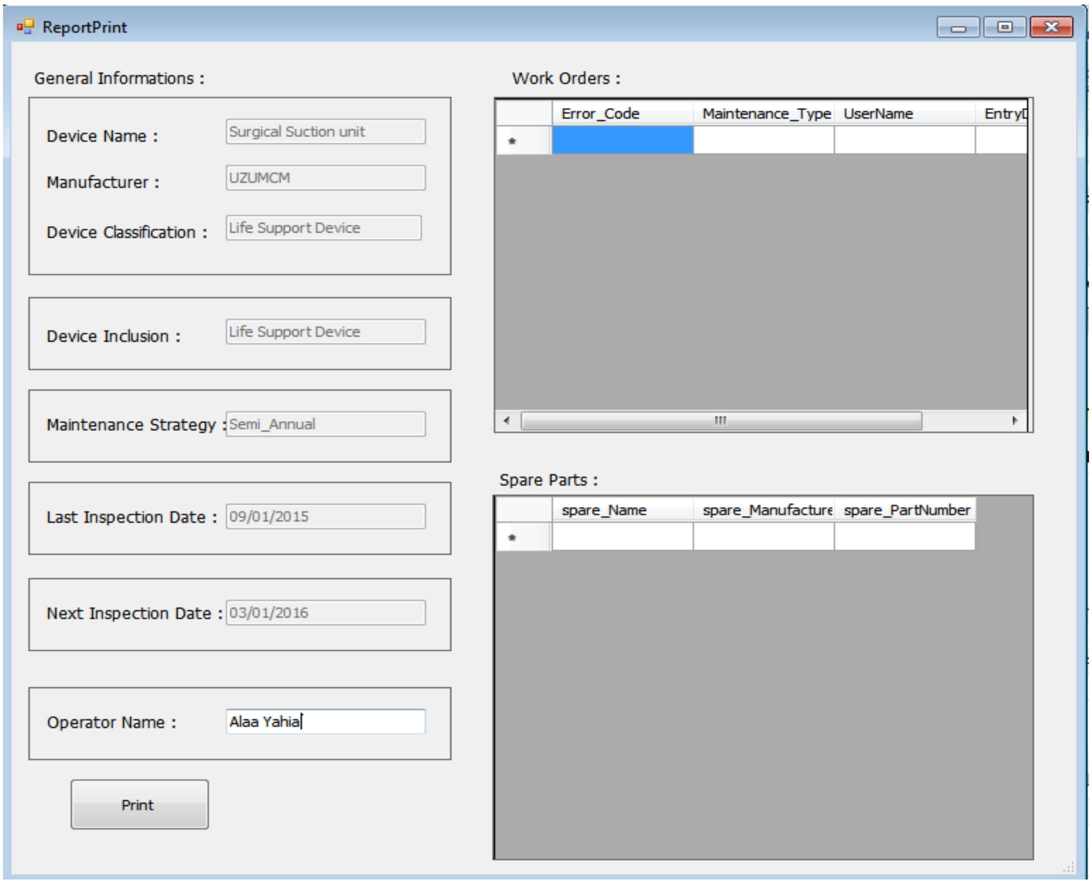


Figure5.10: Final report of surgical suction unit

- Hospital B:

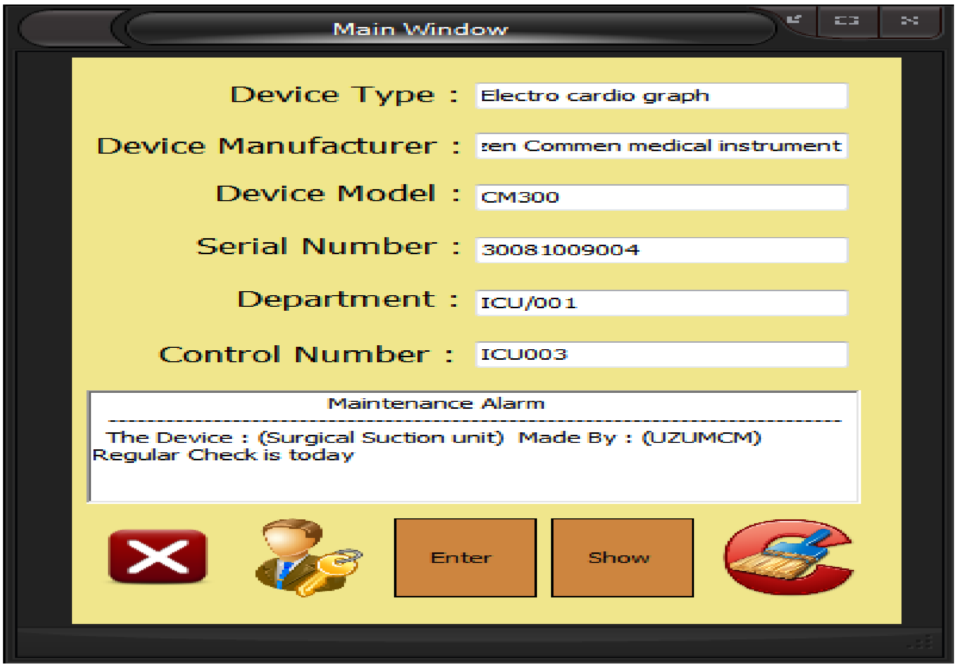


Figure 5.11: Basic information of electro cardio graph

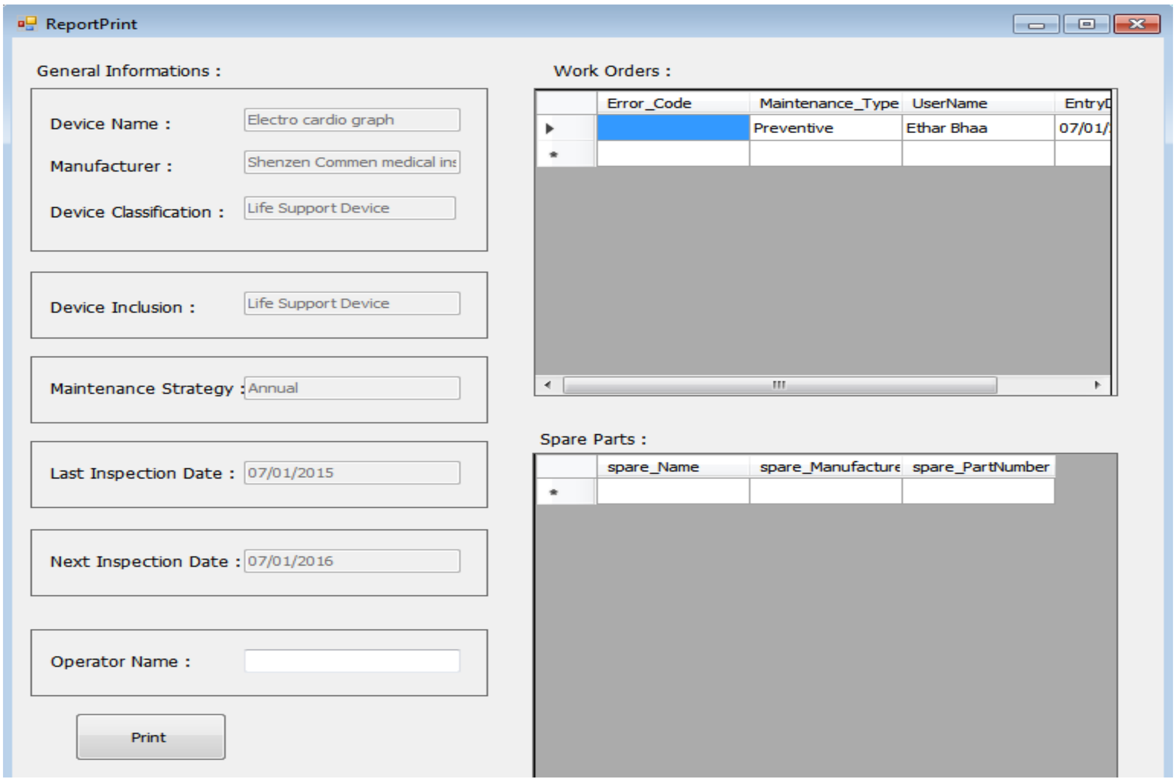


Figure 5.12: Final report of electro cardio graph

Figure 5.13: Basic information of defibrillator

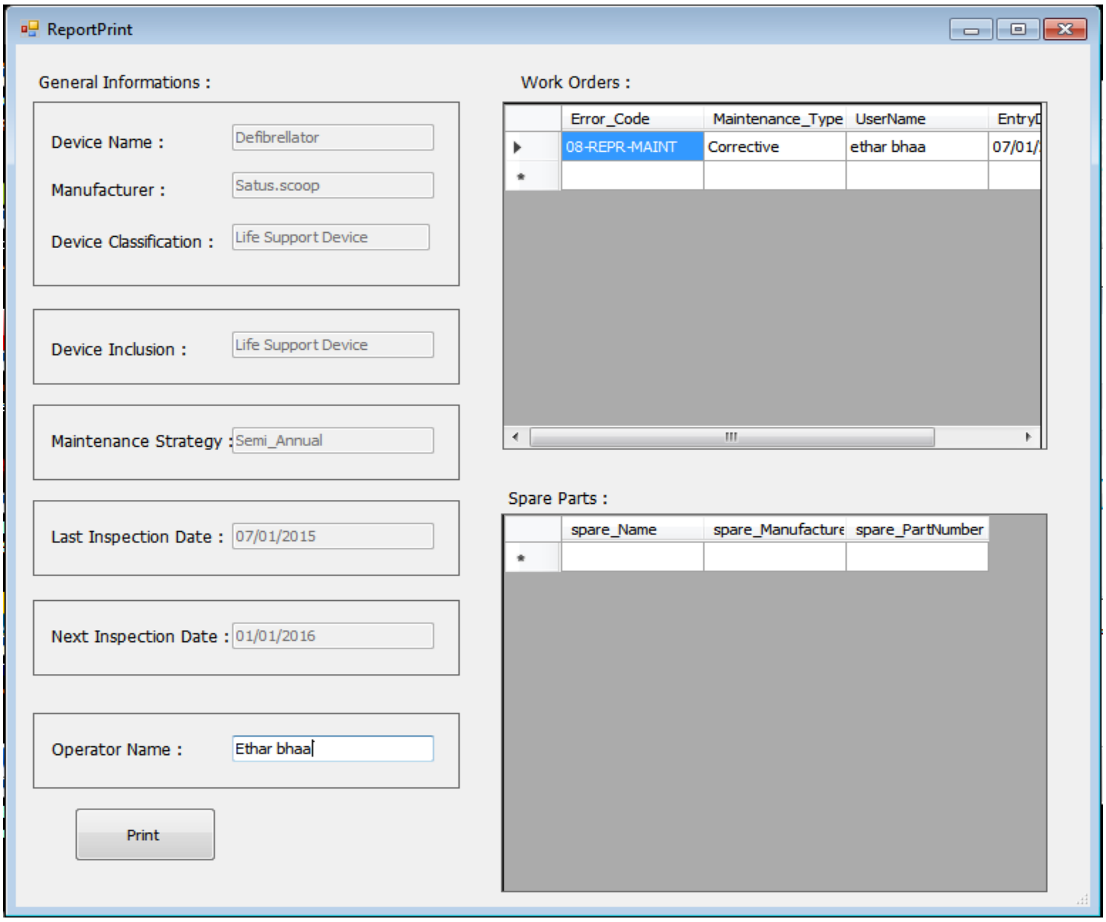


Figure 5.14: Final report of defibrillator

Figure 5.15: Basic information of electro surgical generator

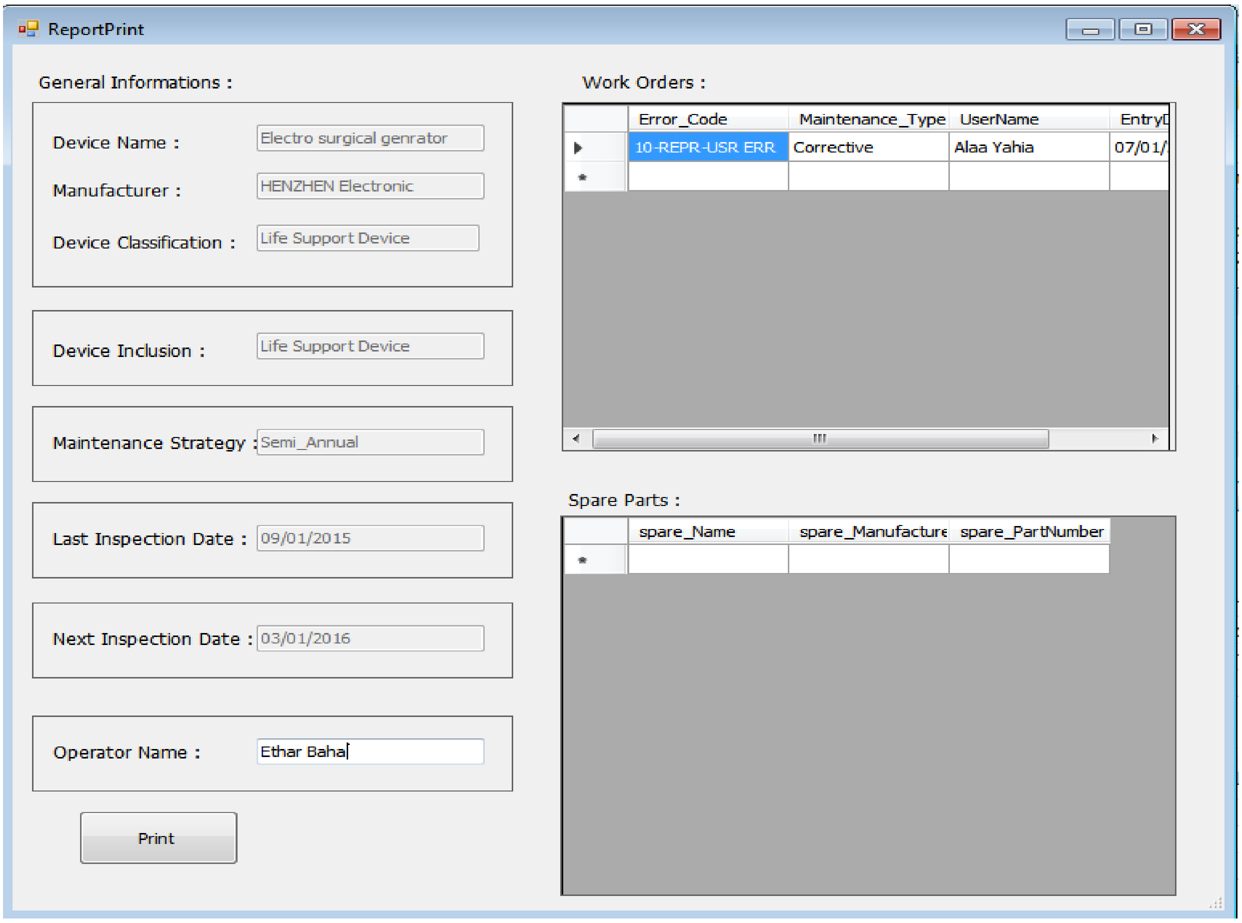


Figure 5.16: Final report of electro surgical generator

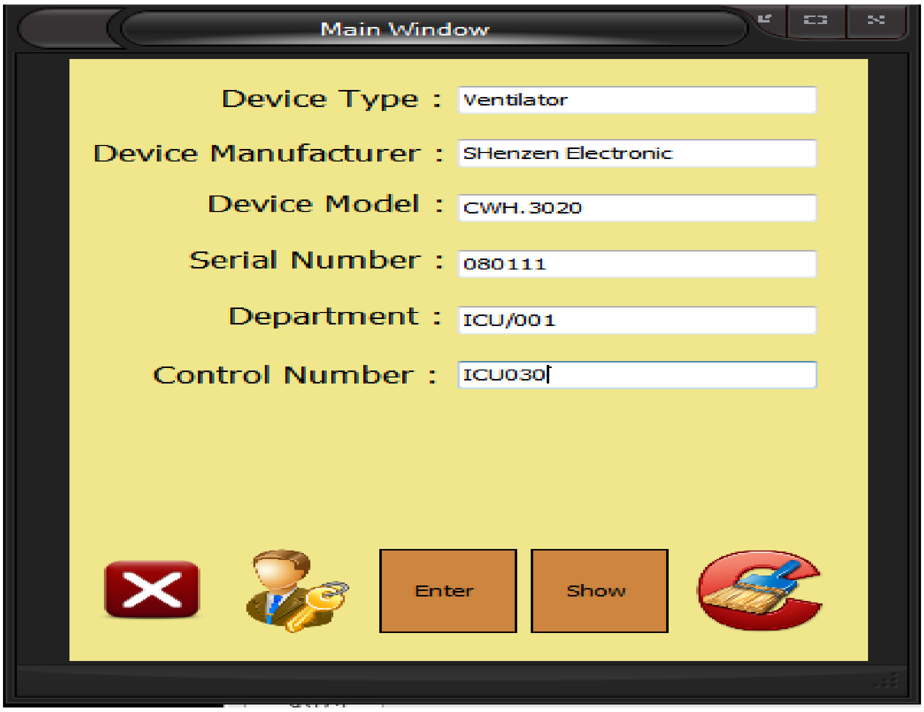


Figure 5.17: Basic information of ventilator

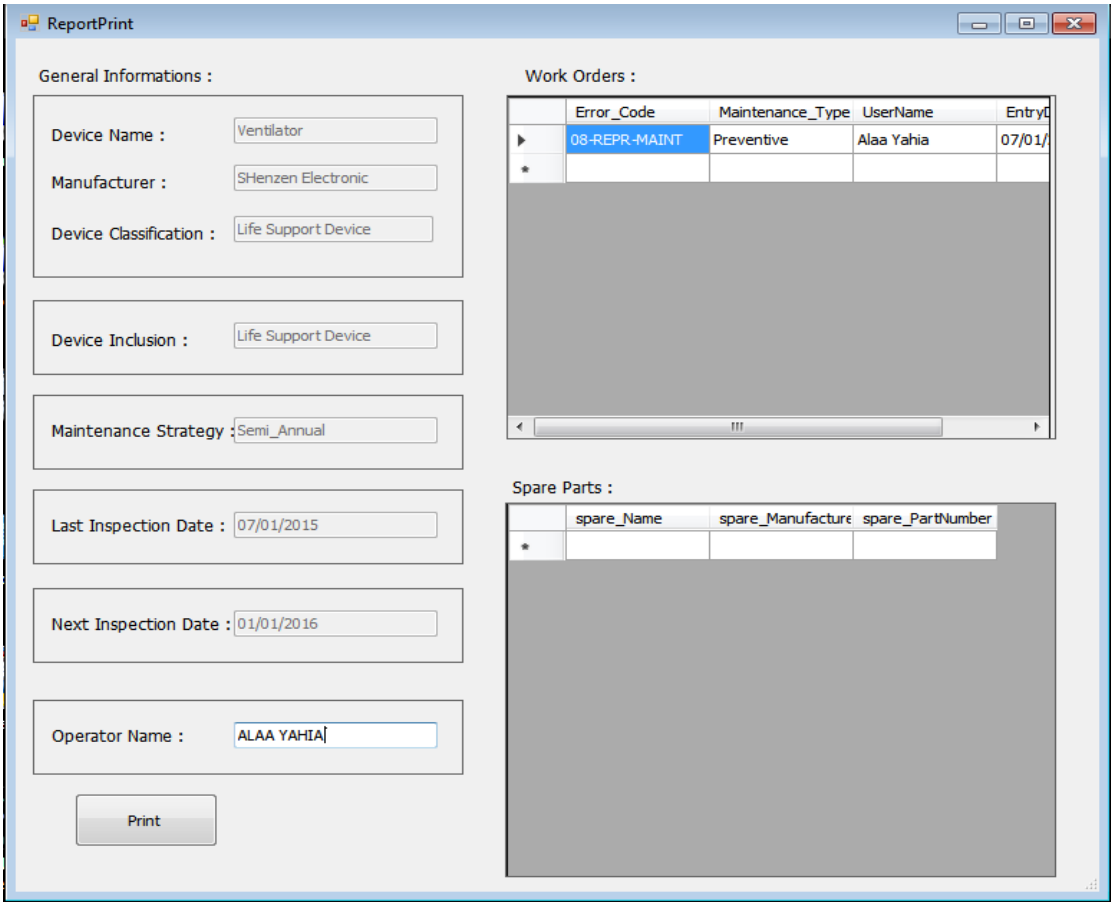


Figure 5.18: Final report of ventilator

Figure 5.19: Basic information of therapeutic ultrasound

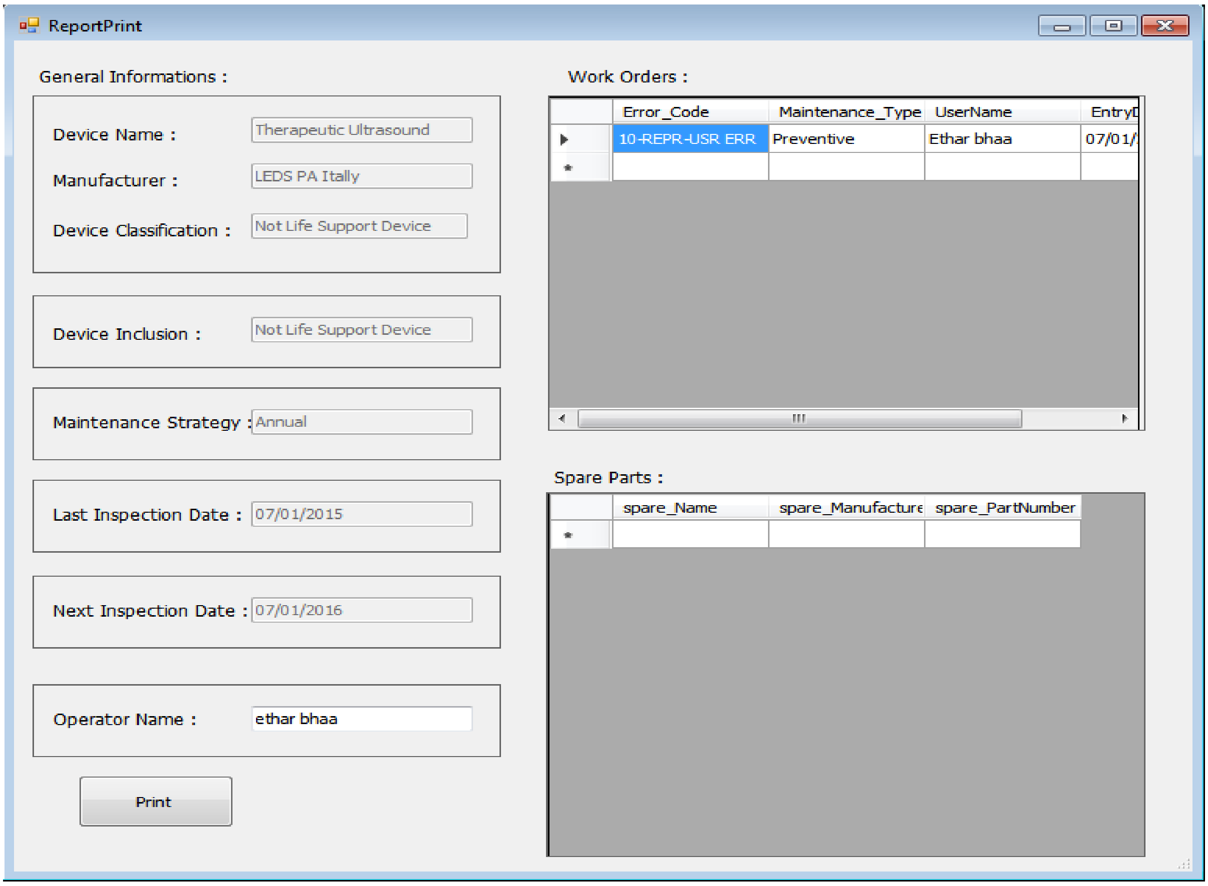


Figure 5.20: Final report of therapeutic ultrasound

- Hospital C:

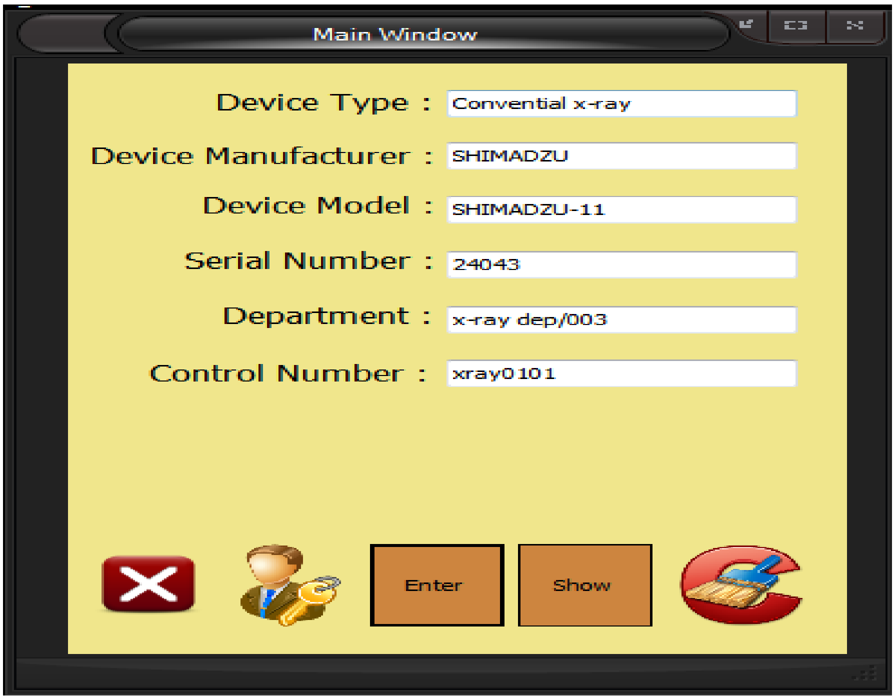


Figure 5.21: Basic information of conventional x-ray

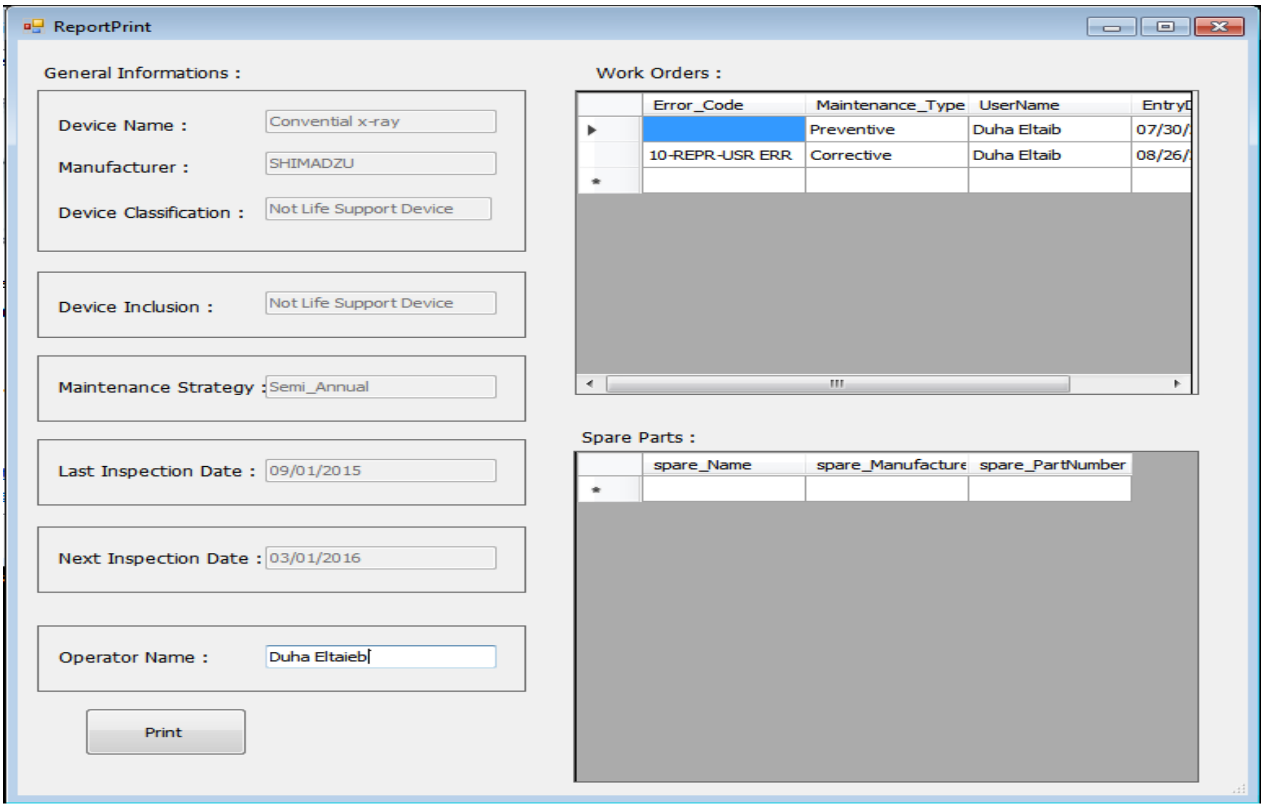


Figure 5.22: Final report of conventional x-ray

Figure 5.23: Basic information of infusion pump

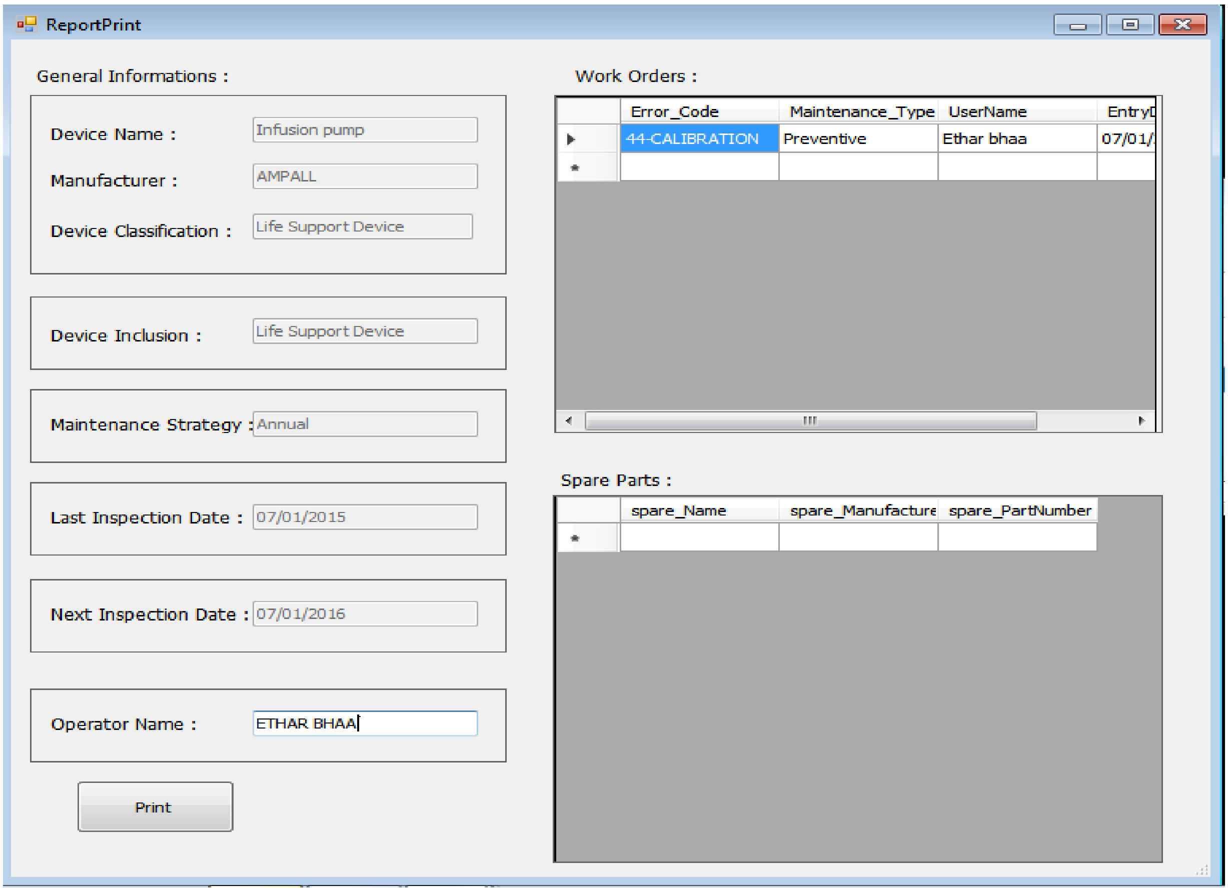


Figure 5.24: Final report of infusion pump

Figure 5.25: Basic information of patient monitor

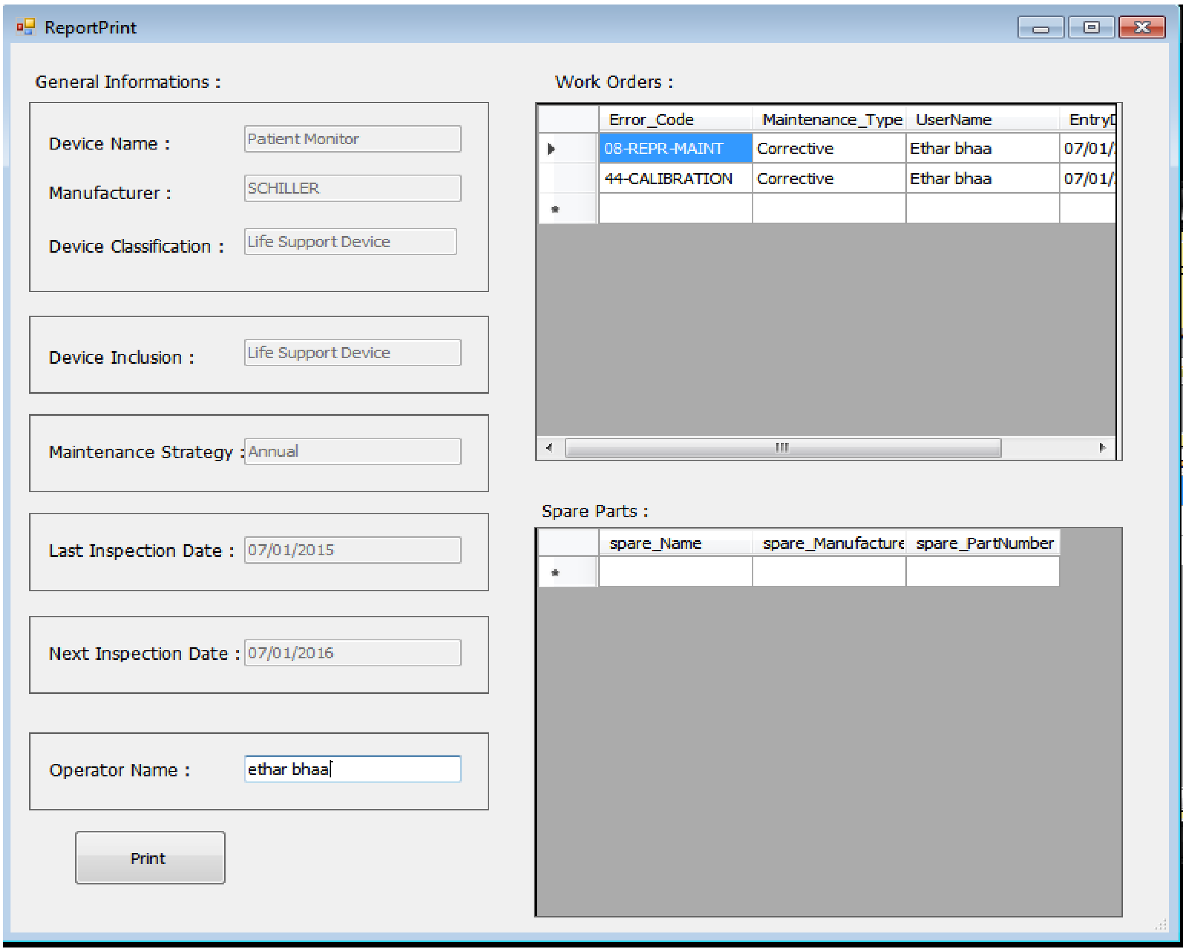


Figure 5.26: Final report of patient monitor

Figure 5.27: Basic information of patient monitor

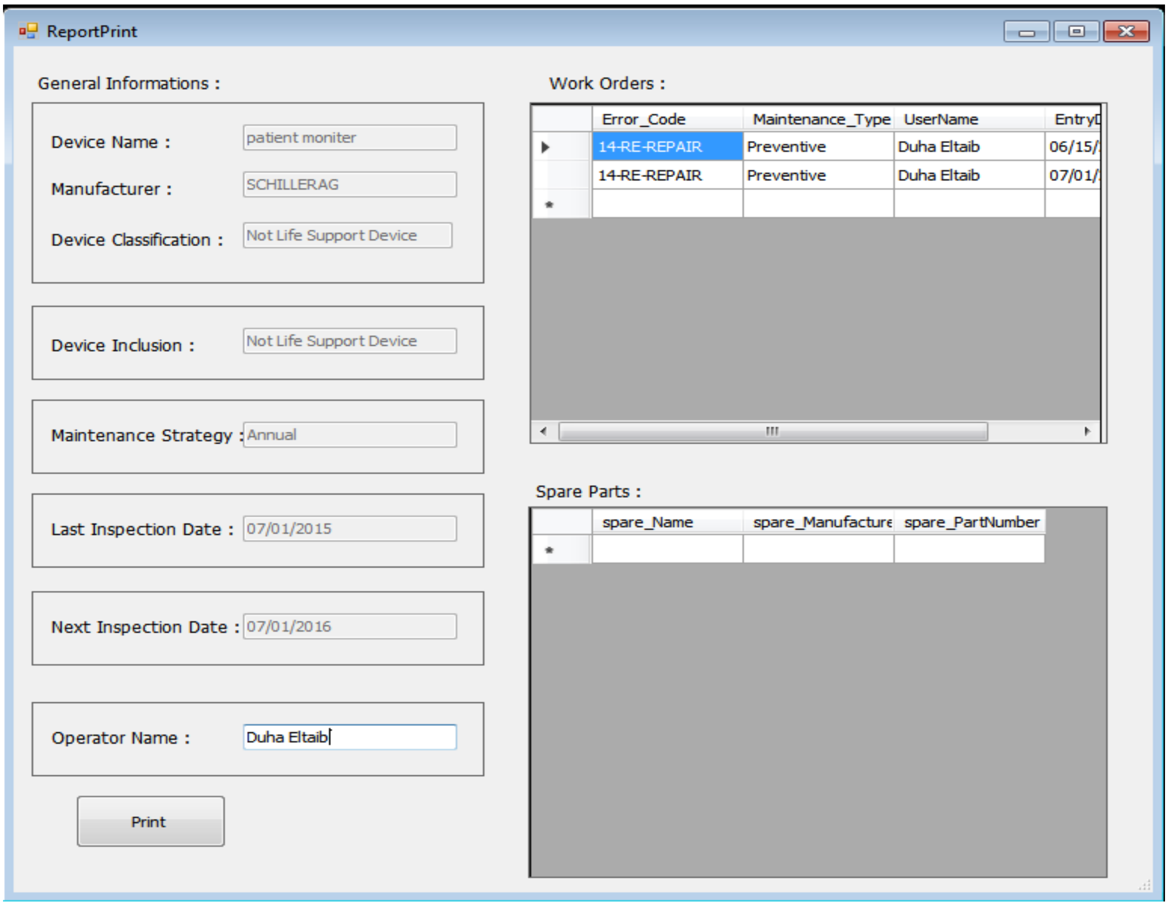


Figure 5.28: Final report of patient monitor

Figure 5.29: Basic information of electrosurgical unit

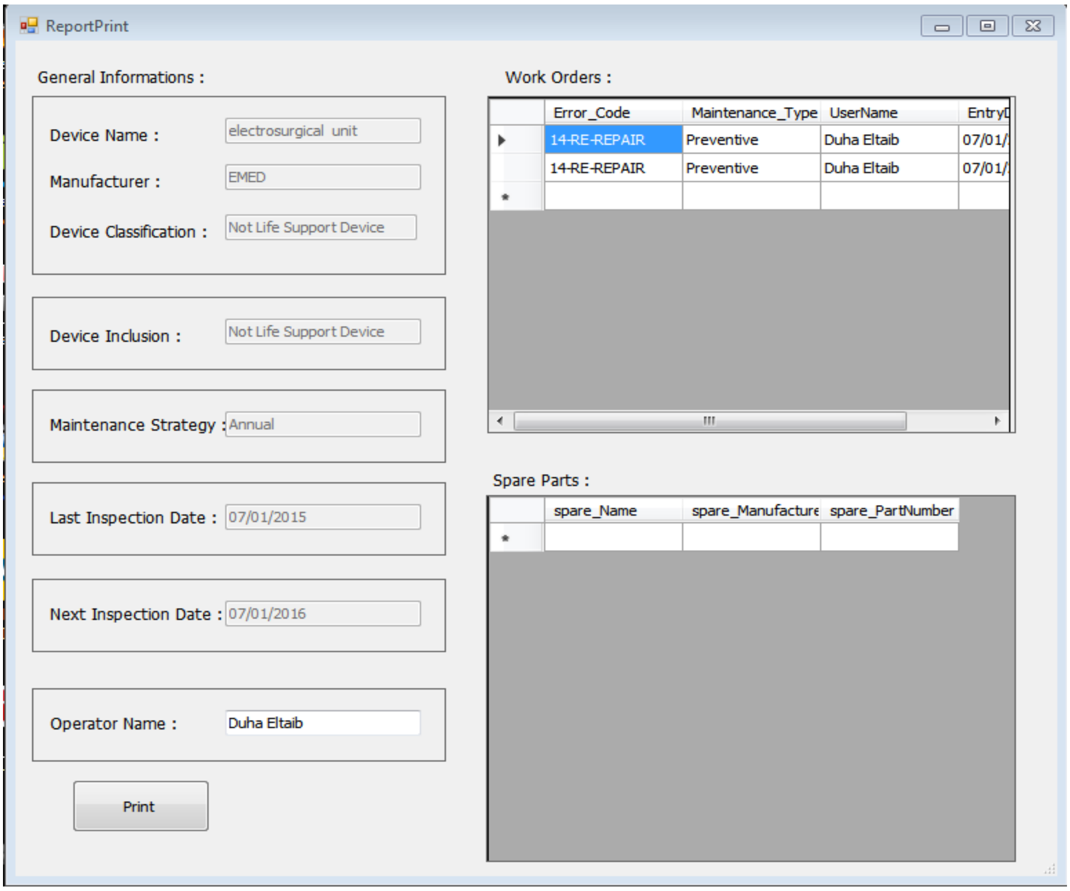


Figure 5.30: Final report of electrosurgical unit

- Hospital D:

Figure 5.31: Basic information of infant incubator

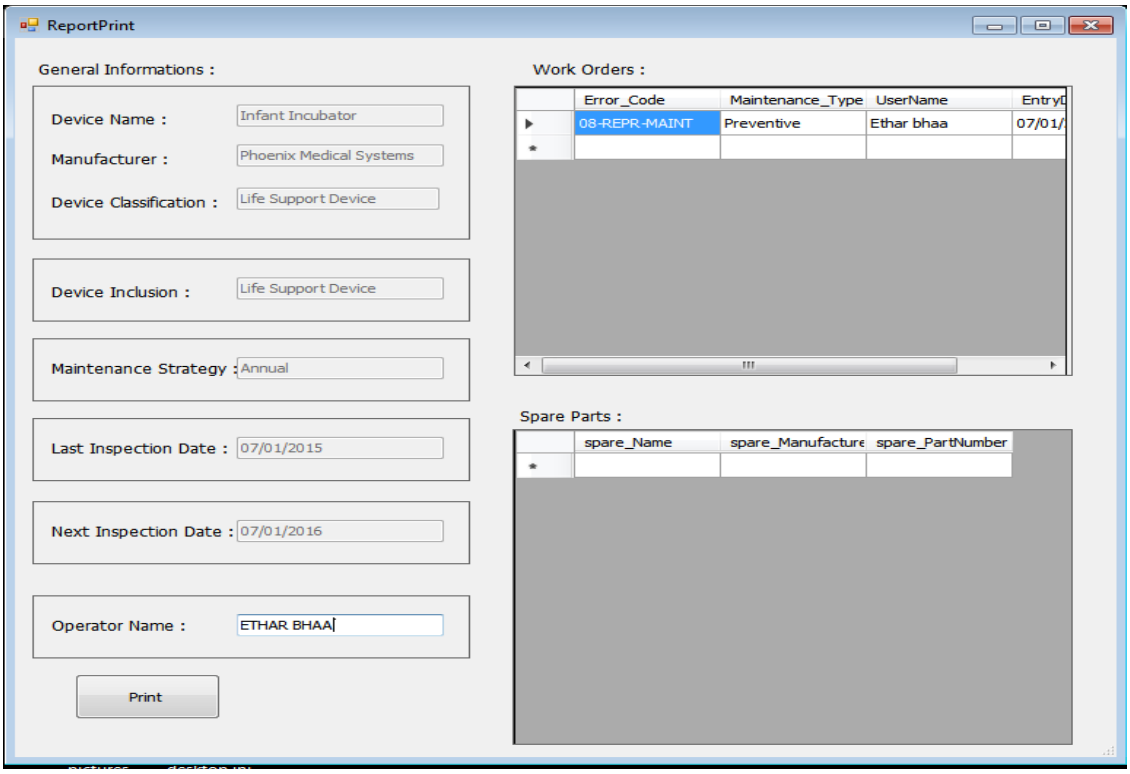


Figure 5.32: Final report of infant incubator

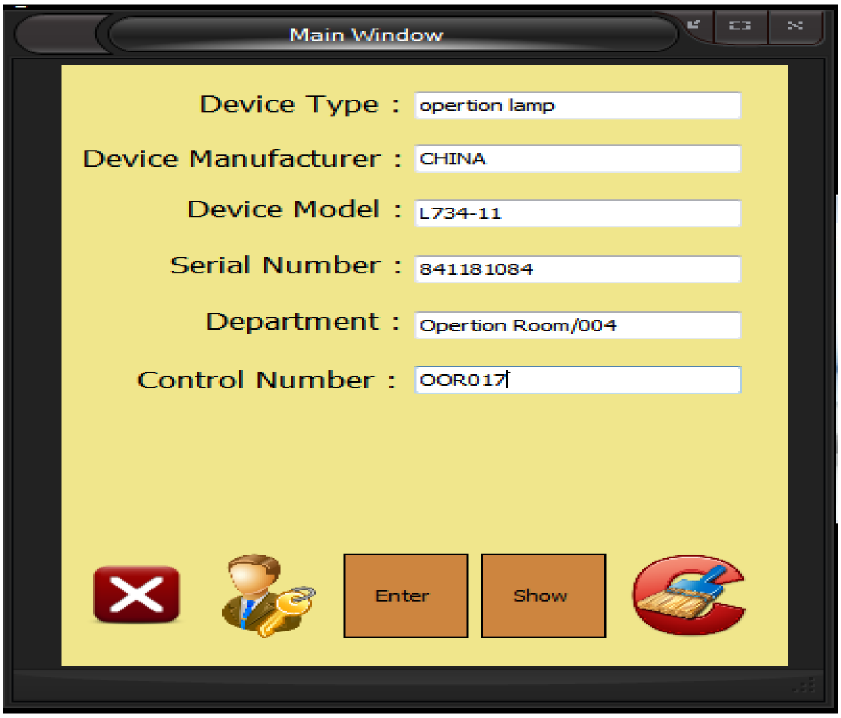


Figure 5.33: Basic information of operation lamp

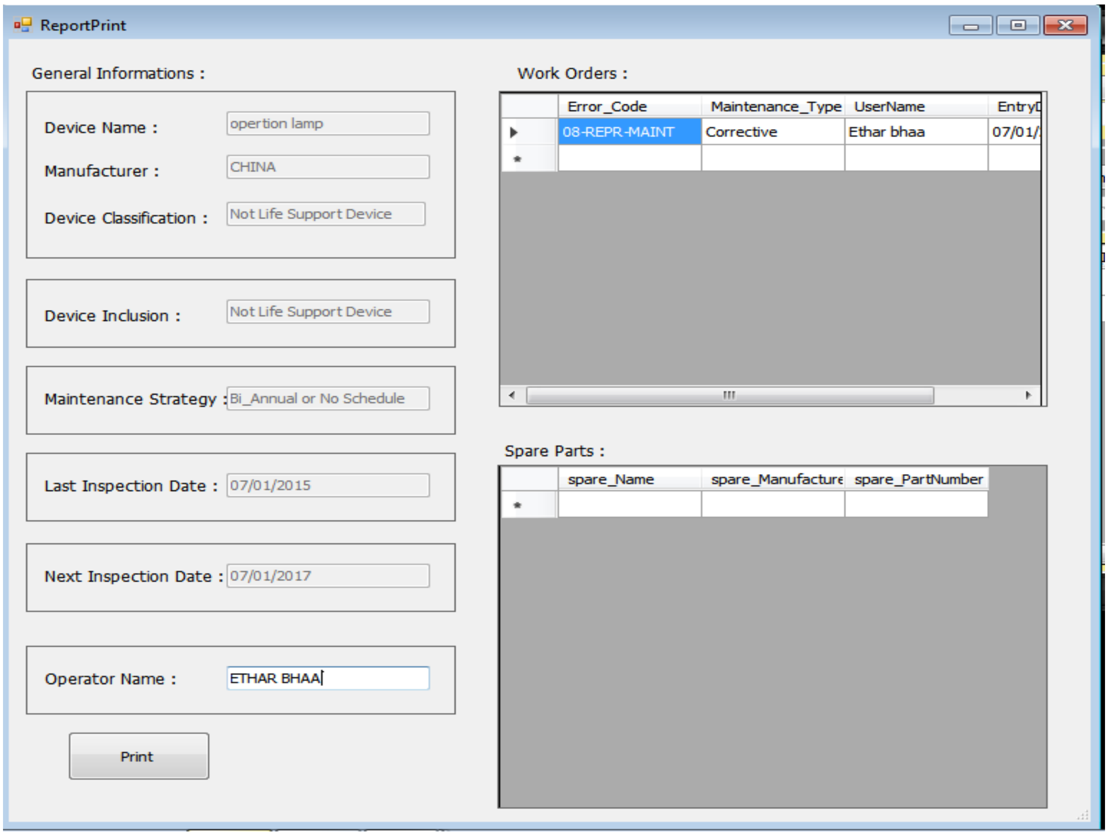


Figure 5.34: Final report of operation lamp

Figure 5.35: Basic information of hot air oven

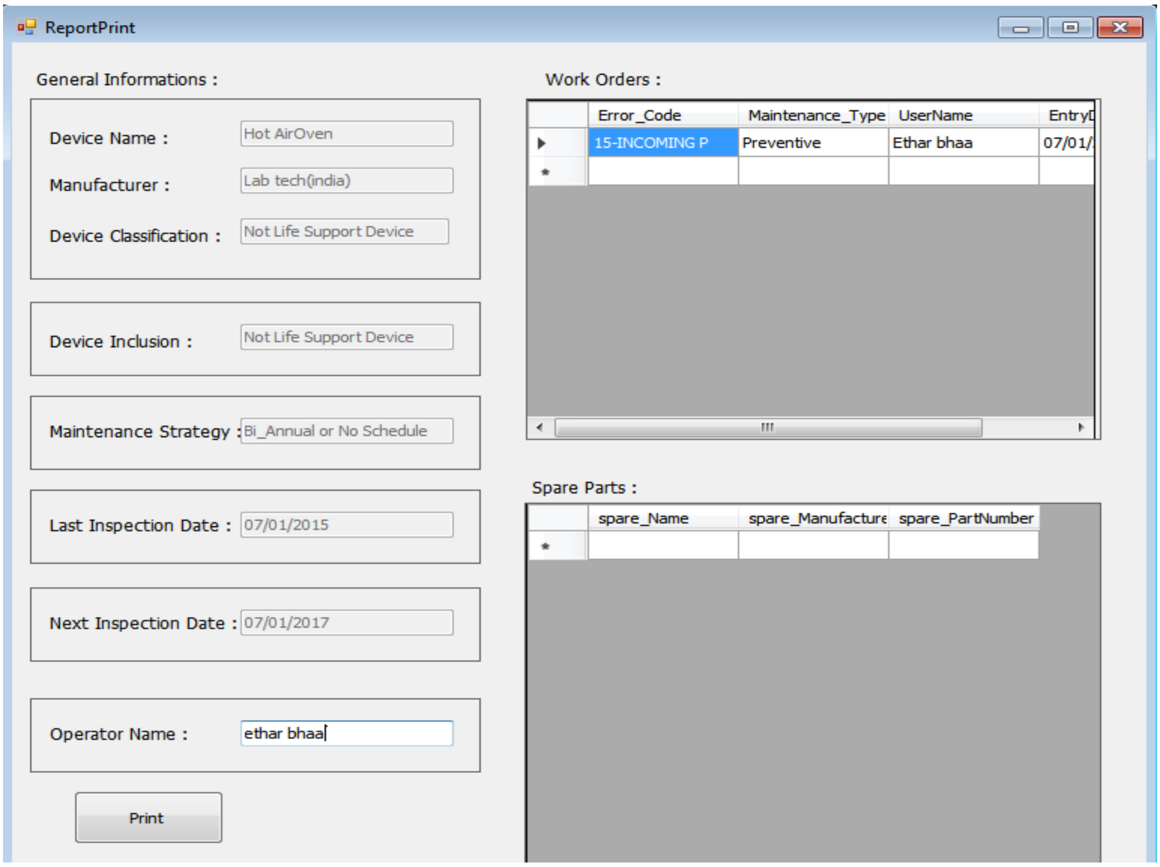


Figure 5.36: Final report of hot air oven

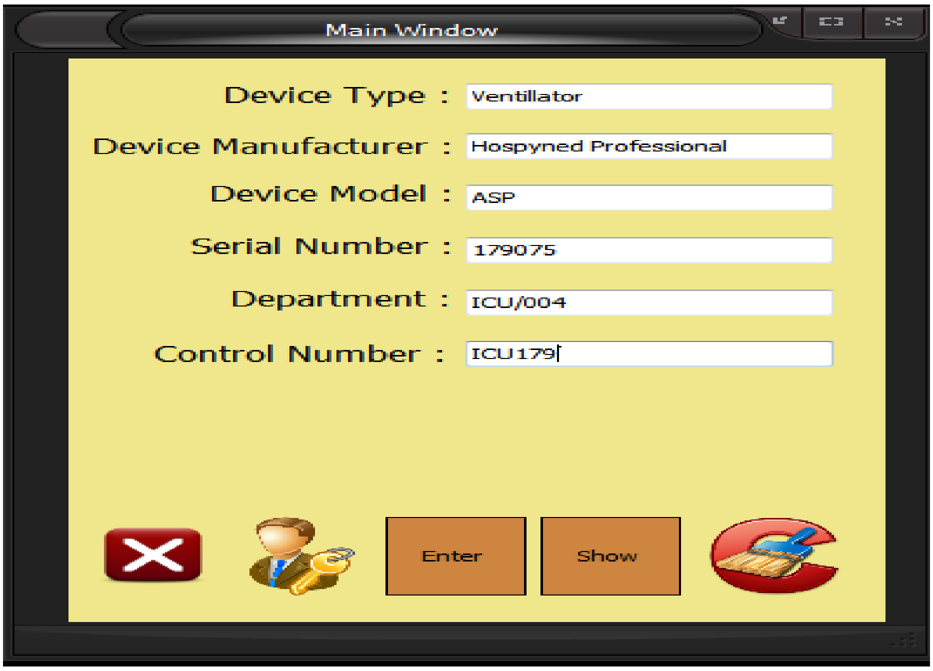


Figure 5.37: Basic information of ventilator

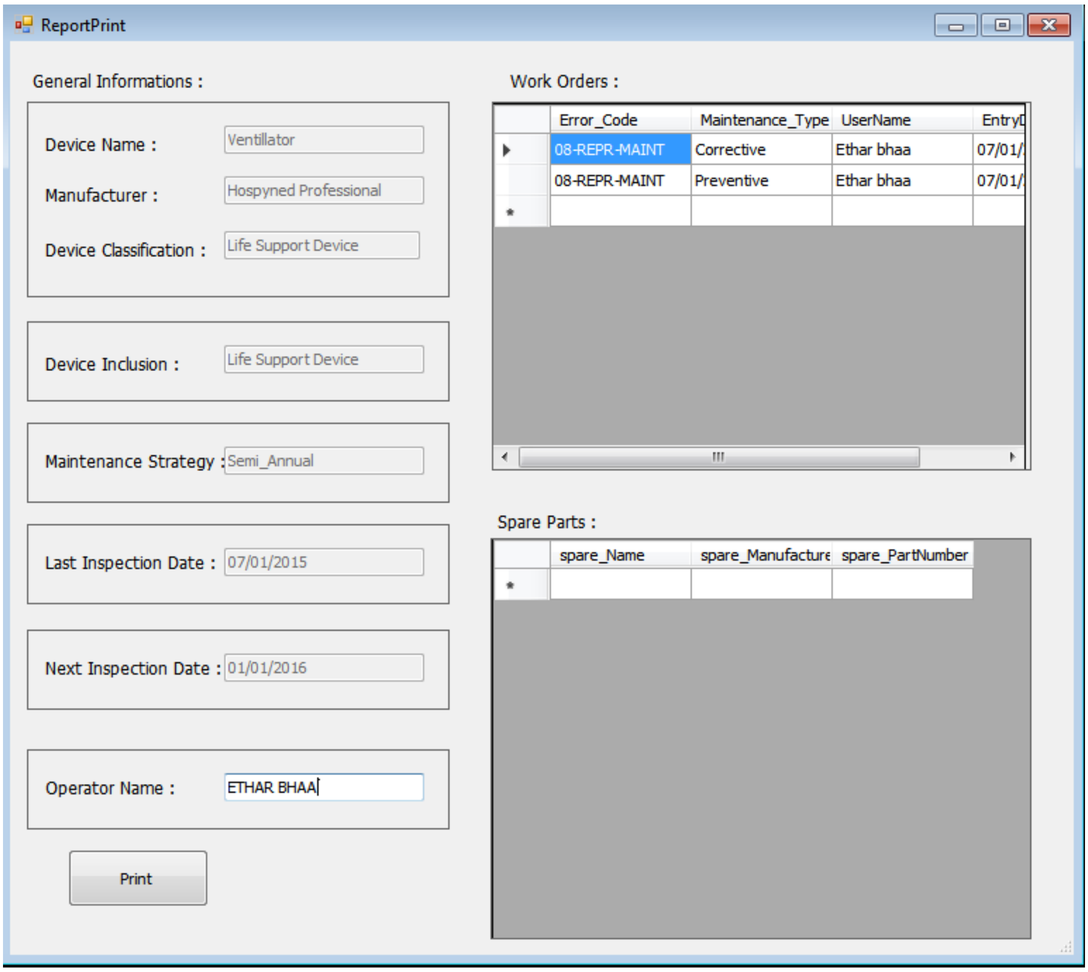


Figure 5.38: Final report of ventilator

Figure 5.39: Basic information of patient monitor

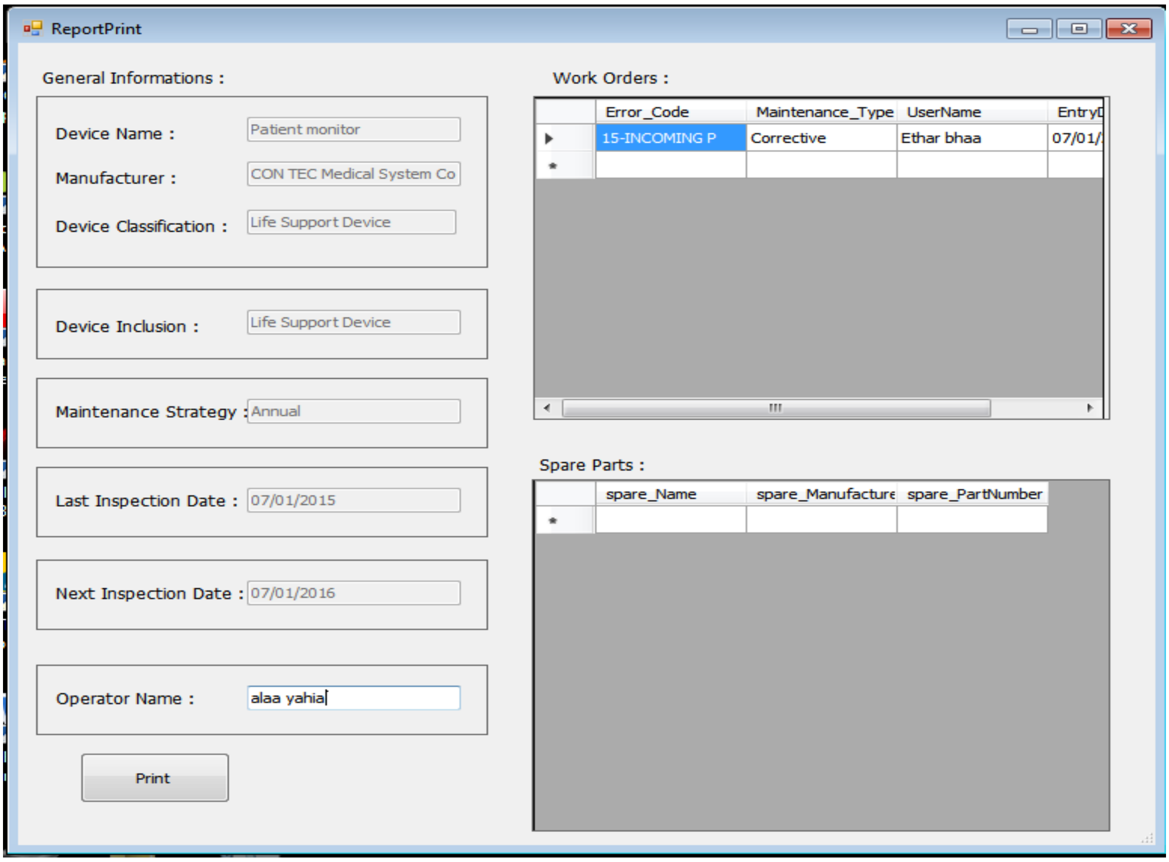


Figure 5.40: Final report of patient monitor

	Control Number CN	Documentation	Spare parts	Manuals
Hospital A	Has control numbers for its devices	Has clear documents for its devices	The spare parts that had been used did not documented	Do not exist
Hospital B	Has control numbers for its devices	Does not have clear documents for its devices	The spare parts that had been used did not documented	Do not exist
Hospital C	None	Does not have clear documents for its devices	The spare parts that had been used did not documented	Do not exist
Hospital D	None	Does not have clear documents for its devices	The spare parts that had been used did not documented	Do not exist

Table (5.1) shows the comparison between hospitals

Found that all of these hospitals do not have an ideal operating number that is based on the standard specifications for making the operating numbers. Knowing that operating number is a very important in the QC program because it is one of the important device information's that the program tracks it.

Hospital A and B have none ideal operating numbers for their devices where these hospitals made and gave this numbers to its devices according to its distribution in the different sections.

Also found that all of these hospitals do not have clear documents for their devices that contains the device history starting from entering the device and start using it, all preventive and corrective maintenance procedures that had been conducted, the spare parts that had been used, all the faults that had occurred and the other important information that may need it for the evaluation of the device.

Hospital A does documentation only for corrective maintenance procedures that had been conducted.

Hospital B, C and D do not have any documents for their devices they only care about conducting corrective maintenance procedures to repair devices failures.

All of these hospitals replace the devices just when completely stop working not when they exceed their life span. In general all medical devices in these hospitals did not exceed the life span but they work with low efficiency because they do not inspected periodically and preventive maintenance procedures are not performed periodically.

The hazardous devices in these hospitals do not receive special care to avoid injuring the operators and patients.

Most of the devices' manuals that assist in the maintenance do not exist

5.2 Discussion:

This medical equipment quality control program aims at identify the models to improve current inspection and evaluation strategies for medical devices in healthcare facilities. Inspection and preventive maintenance is a fundamental aspect of such a program. The results are obtained from applying the model in 4 hospitals that working with different medical devices. It uses a risk-based assessment for determining the maintenance intervals of the devices to provide high-quality, cost-effective inspections based on risk and function, historical data on problems found, and the effect of maintenance on the reduction of problems. The program introduces the process to determine what devices will be managed by classifying them so all devices must be evaluated. Medical devices which do not function properly may cause the lost of human life - may it be done by causing a direct damage or by leading to an error in the diagnosis of a disease. The general procedure described in this work refers to a variety of device types and may be easily adopted to any institute needs and applied in biomedical/clinical engineering departments of hospital and sick funds. As this program becomes effective, the reliability of the equipment increases. This medical equipment quality control program can be significantly improved by proper employment of optimization techniques. Inspection of a large number of medical devices, if fairly planned and executed, can be cost-effective, efficient and can assure reliability of equipment, and safety of patients and operators.

CHAPTER SIX

CONCLOUSION AND FUTURE WORK

6.1 Conclusion:

This computerize inspection program and procedures for medical devices (CIPP) has been achieved in three main directions: design the inspection and PM system for health care institutions, apply and test it on medical devices in some health care institutions and analyze the results. Schedule maintenance reduces incidence of failures through inspections designed to detect potential problems before they occur.

The System has resolved the issue of time so that there is no need to recollect the information's every time you need to use the devices because the system made the information's is available and saved. Also the system reduces the duration in detecting errors and failures happened by the (error log) feature that shows them. This decreased the repair time because the information needed will be available immediately. The quality control, and PM in health care institutions will be improved and the loss of data will reduce.

6.2 Future works and Recommendations:

This program can be developed to be more effective by adding a telecommunications system that connect all the health care institutions in Sudan with central quality control organization which evaluates and control them. Also allows them to exchange information resources.

Also the system can be improved by adding more features and improved to the software itself, to the forms and to the security part.

The system flexibility can be increased by adding it to smart phones of biomedical engineers as an application and connect between the systems by internet networks as an inspection and preventive maintenance software.

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Appendix:-

Introduction to the programming language(C#):

C# is a multi-paradigm programming language which is based on object-oriented and component-oriented programming disciplines. It provides a framework for free intermixing constructs from different paradigms and It uses the “best tool for the job” since no one paradigm solves all problems in the most efficient way. The C# language has been used to design this medical equipment quality assurance program.

.1Desgin goals:

- C# was intended to be a simple, modern, object-oriented language.
- The language and implementation had to provide support for software engineering principles like strong type checking, array bounds checking and automatic garbage collection.
- The language was intended for development of software components suitable for deployment in distributed environments.
- Source code portability was important for programmers who were familiar with C and C++.
- Support for internalization to adapt the software to different languages.

C# Features:

- The big idea of C# is that everything is an object.
- C# is a programming language that directly reflects the underlying Common Language Infrastructure (CLI). Most of its intrinsic types correspond to value-types implemented by the CLI framework.
- Type-safety: C# is more type safe than C++. Type safety is the extent to which a programming language discourages or prevents type errors.

- Managed memory is automatically garbage collected. Garbage collection addresses the problem of memory leaks by freeing the programmer of responsibility for releasing memory that is no longer needed.
- Unlike Java, C# does not have checked exceptions. This has been a conscious decision based on the issues of scalability and version ability.
- Multiple inheritances are not supported, although a class can implement any number of interfaces. This was a design decision to avoid complication and simplify architectural requirements throughout CLI.

Advantages of C#:

- It allows design time and run time attributes to be included.
- It allows integrated documentation using XML.
- No header files, IDL etc. are required.
- It can be embedded into web pages.
- Garbage collection ensures no memory leakage and stray pointers.
- Due to exceptions, error handling is well-planned and not done as an afterthought.
- Allows provision for interoperability.

NET FRAMEWORK:

NET framework is a software framework primarily for Microsoft Windows. It includes a large library & provides language interoperability across several programming languages. Programs written for the .NET Framework execute in a software environment, as opposed to a hardware one for most other programs. The .NET Framework is intended to be used by most new applications created for the Windows platform.

The framework allows platform-agnostic & cross-platform implementations for other OS'. The availability of specifications for the CLI, & C# make it possible for third parties to create compatible implementations of the framework & its languages on other platforms. [22]

Definitions

A meaningful preventive maintenance program requires consistent terminology. This section contains practical definitions of terms used in this manual.

Calibration:

The process of determining the accuracy of a device by comparing it to a known measurement standard . The device is then adjusted to agree with the standard within a recommended tolerance. Minor adjustments to achieve the specified accuracy are considered part of the calibration process. Major readjustments and parts replacement are considered repairs and are not included in the calibration process.

Class I medical equipment:

Electrical medical equipment with accessible conductive parts or internal conductive parts protectively grounded in addition to basic insulation.

Class II medical equipment:

Electrical medical equipment that uses double insulation or reinforced insulation for protection against electric shock in addition to basic insulation .

Clinical equipment:

Medical equipment used for diagnosis, treatment, or monitoring of a patient . Clinical equipment is further broken down to life-support and non-life-support equipment.

Clinical risk:

The risk associated with the clinical use of the equipment, taking into account how invasive the equipment is to the patient.

Corrective maintenance:

Also known as repair . Corrective maintenance entails isolating the cause of the device failure. Affected components are adjusted or replaced to restore normal function. A performance inspection is performed following corrective maintenance before the device is placed back into service to ensure proper operation of the device.

Device inclusion:

How a device is used determines whether or not to include the device on the managed inventory. The device inclusion categories include clinical equipment, utilities equipment, and general equipment. Most equipment on the inventory will be classified as clinical equipment.

Electrical safety testing:

Testing of equipment to assure it is electrically sound to avoid the possibility of micro shock. Electrical safety testing involves testing the ground wire resistance, current leakage to the chassis, and current leakage to the patient leads.

Equipment inventory:

A record of medical equipment used in a facility. The inventory may include equipment that does not receive scheduled maintenance as well as managed equipment for tracking purposes.

Estimated time:

The estimated amount of time needed to perform the scheduled maintenance.

The estimated time includes the time from test set up to the conclusion of the maintenance.

Exception testing:

Following scheduled performance inspections, only failures are documented. Equipment that has not been documented as needing repair or adjustment is assumed to be safe and ready for use. This method of testing is useful when performing preventive maintenance and performance inspections on a large number of devices.

General equipment:

Equipment that cannot be classified as either clinical or utilities equipment .

Incoming inspection:

A performance test performed on a piece of medical equipment before being put into use to verify the safety of the device.

Life support equipment:

Medical equipment that takes over a function of the human body and whose loss will cause immediate death

Maintenance interval:

Also referred to as testing frequency or the length between scheduled maintenance . Most commonly, the maintenance interval is given as a length of time (i.e. every 6 months), but can also be given in hours of equipment operation (i.e. every 10,000 hours).

Managed inventory:

A record of medical equipment used in the facility that only includes equipment requiring schedul e.

Mean time between failures:

The average time between failures of a device or system . This is used as an indication of reliability.

Performance inspection:

A procedure to ensure a device operates appropriately. The device should meet safety and performance requirements of regulatory agencies, the healthcare facility, and the manufacturer. Performance inspections will vary by device type and each device type should have a written procedure that includes the characteristics that are tested, how to test them, and acceptable operational limits. Performance inspections are performed periodically to ensure proper operation of devices prior to being put into service for the first time, after a repair, or anytime the operation of the device is questioned.

Physical risk:

The risk associated with device failure.

Preventive maintenance (PM):

Periodic procedures to reduce the risk of device failure . The maintenance interval may be based on time (e.g. every 12 months) or operational usage (e.g. every 1,000 hours). Preventive maintenance is designed to ensure continuous operation of equipment. Preventive maintenance tasks may include replacing parts, lubricating, and adjusting.

Preventive maintenance excludes tasks normally carried out by the user.

Problem avoidance probability.

The likelihood of a device to fail based on historic data related to medical equipment repair and maintenance.

Procedure:

Maintenance tasks that need to be completed for effective performance testing and preventive maintenance .

Regulatory requirements:

Specific criteria that must be met as set forth in codes and standards. Regulatory requirements often have the power of law behind them from a governing body.

Risk assessment:

The identification and quantification of possible hazards . A risk assessment involves a numerical scoring system to quantify the amount of risk.

Risk management:

A process by which possible hazards are identified and assessed .

Procedures are put into place to minimize the risks from the identified hazards.

Standards:

Guideline documentation of practices agreed upon by industrial, professional, or governmental organizations.

Utilities equipment:

Equipment that supports medical equipment, life support, infection control, environmental, communication, or critical utility systems .

User checks:

Also known as operator checks . Performance checks on medical equipment that can be performed by the clinical user. These are often simple operational checks that do not require the use of tools or test equipment.