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Medical Instrumentation Quality Evaluation System

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Annotation: We touched on the quality system for medical devices, and we visited some laboratories, and it became clear to us that the issue of quality of medical devices is neglected in some medical laboratories. And we found that the group that we mentioned are the basic devices for each laboratory, and most of the malfunctions that occur due to lack of experience in maintaining the device, lack of interest in it, and failure to maintain it. We found through our research that some analysts and engineers do not have sufficient knowledge to deal with these devices, so we wrote this research to be a simple and easy guide for them. To be their assistant to deal with these devices.

We wrote the research to be a guide for using these devices, even if the user does not have enough experience

Introduction

The quality management system is a set of procedures and processes focused on achieving the quality policy and quality objectives to meet customer needs in accordance with the required

conditions. For implementation, the organizational structure, policies, procedures, processes and resources needed are expressed in quality management.

The current system for quality evaluation of medical devices includes several steps that must be taken to verify the efficiency of medical devices. First, the technical specifications of medical devices must be checked to ensure that they allow proper operation. Secondly, the operational and operational procedures of the medical devices must be checked to ensure that they are working properly. Third, health and environmental standards related to medical devices must be checked to ensure that they do not negatively affect users. Finally, security standards for medical devices must be checked to ensure that they are safe and do not cause any harm.

The Quality Assessment System for Medical Devices helps ensure that the results expected from medical devices are obtained. Therefore, this system must be adhered to in order to ensure that medical devices are able to perform their tasks correctly and reliably.

The general objective of quality management is to maintain devices and equipment in good condition and at the lowest costs, within the continuous and continuous follow-up of medical devices and equipment, and not to leave them for a long period without repair, and to complete their repair in the shortest possible time and permanent follow-up.

Create a record of equipment and check its proper performance

Providing an overview of the equipment in the laboratory is the first step in implementing a quality management system for the equipment. The equipment log includes specific details about each piece of equipment (such as maintenance and calibration dates, maintenance frequency, who is responsible for this equipment, etc.) Thus, the equipment record is the most important component of equipment quality management.

When the equipment is registered, each piece of equipment is immediately checked and recorded in the Equipment Register so that it is clear which piece of equipment has priority in maintenance planning.

Creating an Equipment Record is an overview of all the equipment in the laboratory including important details. will be created for each piece of equipment and will contain more detailed information.

Safety and security

Safety and security officer job:

1. Waste work generates waste generated by your laboratory. For chemical waste: identification category of each.
2. Checking if there are national or local systems in place to treat the types of waste that are used Credit them to your labs.

Biosafety officer

Check regularly if cleaning is taking place as scheduled Table The timeline is dated and signed for each planned cleaning. Is the buildingreally clean?

If not, You must inform the laboratory director.

Organize scheduled periodic cleaning of the laboratory with policies and procedures in place

The laboratory should be clean and tidy. This reduces the risk of accidents and injuries associated with laboratories. Moreover, a clean environment also reduces risk

Negative effects on sensitive tests (such as cultures or PCR) throughpollution.

Set up a laboratory cleaning schedule. The laboratory building shouldbe cleaned regularly before

Dedicated and trained staff. However, the laboratory roomsthemselves must be cleaned

By laboratory technicians since they are familiar with the risks andsafety of laboratory procedures.

The essential laboratory needs according to the Biosafety Guide to Dealing with Spills

- ✓ Hypochlorite solution stored in an opaque bottle
- ✓ Respirators
- ✓ Gloves
- ✓ Laboratory gowns
- ✓ Dustpan and brush
- ✓ Chloramine tablets
- ✓ Paper towels
- ✓ Soap
- ✓ Sharps container
- ✓ Biohazard bags
- ✓ Goggles

Chapter Tow

Incubator	
Equipment	It is a device used to grow and Maintain micobial colonies or cell colonies
Label	MODEL/WP25A/Power/180W Voltage/220V/Frequency/50Hz www.faithful.cc
Serial number	20220101150048
Manufaturer	IN China
Manufaturers contact person+cntact	Eng.sohaib +FAITFUL
Temperature	60\65C
Dimension	300x300x300 Mm
Location equipment	Al-Jana medical laboratory
Frequently of maintenance	12 times a year
Power Consumption	220 /230V AC

Laboratory incubator: It is an isolated, closed, box-like thermal device that is used to preserve and multiply microorganisms, or cells, so that it maintains a certain temperature selected according to the type of cultivation used in it, and maintains the humidity and gas content in it, and is one of the devices Of great importance in the laboratory, whether it is in a medical or pharmaceutical laboratory, or any other type of scientific and research laboratories, and therefore it is important to identify the most important types and their uses.

الشكل رقم)1(: جهاز Incubator

Common malfunctions

1- The key is damaged.

2 - Damage to the heater itself.

3 - Damage to the thermostat.

Autoclave	
Equipment	It is a device that uses a physical method to sterilize and kill bacteria and viruses
Label	Model SB20L 2016 CAP20L 2A SEMP 200C 360W 50HZ http://www.jrad.sy
Serial number	
Manufaturer	In syria
Manufaturers contact person+cntact	Eng.mohammed +jrad
Temperature	***120/134***°C
Dimensions	48*48*43cm
Location equipment	Alshefaa medical laboratory
Frequently of maintenance	12 times a year
Weight	30kg
Evaluation time	15minute

مبدأ عمل الجهاز

An autoclave is a device that uses a physical method to sterilize and kill bacteria, viruses, and even spores on objects, using steam and under the influence of pressure inside its chamber, as it sterilizes objects by raising its temperature for a specific period.

Autoclave : (2) الشكل رقم

االعطال الشائعة

Common faults include: heating function failure, abnormal operation of the water level indicator, interlocking light off, air leakage, safety valve abnormal operation, normal exhaust failure, liquid drain

CENTRIFUGE	
Equipment	Device for separating liquid (plasma)from blood
Label	Model:lc-6 Speed:200-4000 Ac 100-240v 50hz
Serial number	2022150800735
Manufaturer	In germany
Manufaturers contact person+cntact	Eng.sohaib +Al-Malak
Max rcf	5200xg
Max rpm	6000rpm
Location equipment	Alshefaa medical laboratory
Frequently of maintenance	12 times a year
Voltage	110-220v 50-60hz
Weight	10kg

مبدأ حمل الجهاز

A centrifuge is a device in which centrifugal forces are generated by rotation, whereby the heavier particles move outwards away from the axis of rotation, while the less heavy particles remain in the middle.

Centrifuge

Common problems include: the cover cannot be opened, the centrifuge tube cannot be taken out, and the medical centrifuge does not work after pressing the switch. More serious problems include bending caused by uneven pressure on the spindle, engine burn, horizontal bucket scraping, and more serious accidents and even injuries.

MICROSCAPE	
Equipment	It Is A Device For Enlarging Small Objects That Can Not Be Seen With The Naked Eye
Label	Xsz-N107t Ac 100-240v 0.2/0.1a 50/60hz
Serial Number	Xsz-N107t
Manufaturer	In Germany
Manufaturers Contact Person+Cntact	Eng.Mohammed+ Novel
Supply Ability:	1000pcs/Month
Precision	12mp
Location Equipment	Al-Jana Medical Laboratory
Frequently Of Maintenance	12 Times A Year
Focus Lenses	4x , 10x ,40x, 100x
Halogen Lamp	100v-240v/ 6v20w

مبدأ عمل الجهاز

A microscope is a tool that helps to see very small objects that the naked eye cannot see, and to enlarge them so that we can study them closely and learn about their details.

Mechanism of Action

The microscope magnifies the size of objects by means of a complex mechanism of lens cascade. In the beginning there are two main lenses. The first is the lens on the side of the eye, and it is the lens through which we look, i.e. the eye lens, and the second is the lens on the side of the element we want to see, that is, a beginning lens and an end lens with a light source, either a mirror or an electric lamp.

Microscope :

1- The fuse burns outside or inside the device.

2- Burning out the lamp.

3- Transformer combustion.

4- The lighting control unit malfunctioned

CBC	
Equipment	It is a complete blood count test davice
Label	MODEL BC 30s TH-0C008841 100-240V 50/60Hz 180VA
Serial number	047-0214620010
Manufaturer	In germany
Manufaturers contact person+cntact	Eng.mohammed+ mindray
Device dimensions	41.5cm*45.7cm*39.1
Weight	25kg
Location equipment	Al-Jana medical laboratory
Frequently of maintenance	12 times a year
Image saving capacity	3500 picture
Analyzes per hour	60 analyzes

blood count) CBC

(Complete

The CBC consists of three mail systems,

-A hydraulic system

-A pneumatic system

-electrical system

As for the hydraulic system, the blood sample is taken, mixed with some chemicals, and analyzed into its basic compounds of red and white blood cells and platelets for the counting process.

As for the electrical system, it analyzes and calculates the signals resulting from the counting process. In addition to that, there is a pneumatic pressure system, where the device has an air pump with a constant pressure rate. The result of this examination is printed through a printer containing tables and graphs of the results.

جهاز CBC :

أعطال الجهاز

1- (clot)

2- (valves)

3- (chamber)

4- The solution has expired

The breakdown and maintenance part

Maintenance plays a major role in maintaining equipment and devices, and its importance increases with the increase in the quantity,type and cost of machines, which makes it necessary to maintain themfor as long as possible in good condition. That is, the operation process is carried out in an appropriate manner and maintained in a timely manner, taking into account the preservation of devices and equipment, as medical devices are constantly increasing in hospitals, and their development, complexity and costs are increasing, so itrequires a special management to maintain them by providing all the necessary capabilities for them and the presence of trained human energy to maintain On medical devices and dealing with them according to modern methods of biomedical engineering managers

Introduce the necessary modifications and developments to evaluate the equipment in order to reduce the causes of recurring breakdowns.

- Developing and simplifying repair methods in order to extend the life of equipment and to provide spare devices as soon as they are needed. The maintenance of medical devices is considered one of the important operations to maintain the shelf life of the production requirements, i.e. the operation process is carried out in a propermanner and maintenance is done in a timely manner, taking intoaccount the maintenance of devices and equipment, whether mechanical, electrical, electronic or medical, in good technical condition, and the maintenance process depends on the size of the facility and the nature of operations that you make.

The basics of dealing with maintenance

If the device is idle

a) We start repairing from outside Power Cord

b) We examine Power from the inside

c) Check the battery, if any

If the device does not give the required readings

a) We examine Power from the inside

b) Check the battery, if any

c) We make sure of Software by making an adjustment

If the device is mechanically broken

a) We are working on it

Some auxiliary devices for checking laboratory equipment malfunctions

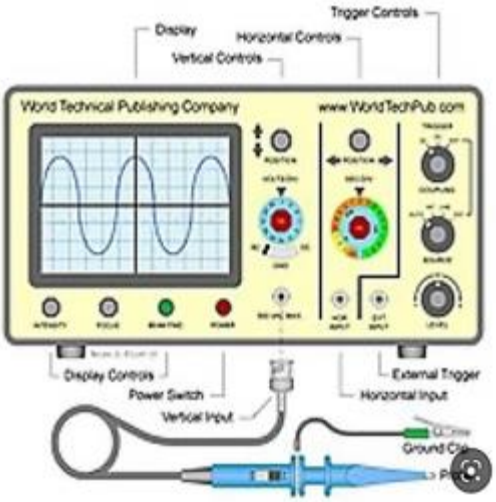
Drenvis tester

Multimeter

Drenvis tester / It is used to ensure that the current reaches the device

Multimeter / An electronic device used to measure resistors, capacitors and electronic parts and to detect faults in them

Electronic caustic



Oscilloscope

A device used for soldering electronic parts and using solder with it .

A device used to measure the incoming and outgoing signal of electronic parts

A set of tools:

A set of tools that help the engineer to complete the maintenance process

Recommendations

1. Adding a requirement to clarify the procedures for detecting device calibration deviation within the specifications for any tende for medical devices.
2. Adding a requirement to train technicians or engineers to conduct calibration deviation detection within specifications to any tender for medical devices.
3. Adding an item to the maintenance and warranty contracts that requires the supplier company to perform calibration in the event that the detection of the calibration deviation indicates the need for it.
4. Set a schedule for periodic inspection by technicians or engineers trained on the accuracy of the devices and ensure that there is no standard deviation in them.
5. Putting a sticker on each device indicating the last time, then examining the extent of the standard deviation and the last time the device was calibrated.

Conclusion

We conclude from the above study on the necessity of having aspecial division for the calibration of laboratory medical devices with the provision of all necessary reference devices in the calibrationprocess with the presence of specialists who are able to conduct tests of the above-mentioned devices and other devices available in laboratories, and this is the importance of calibrating laboratory medical devices for the patient and the doctor because it gives confidence To the doctor that the device that examined the patient's sample gives accurate results, and therefore the diagnosis and treatment of the patient is more accurate and more effective, and works on the safety of the patient and the doctor from dangers.

We touched on the quality system for medical devices, and we visitedsome laboratories, and it became clear to us that the issue of quality ofmedical devices is neglected in some medical laboratories. And we found that the group that we mentioned are the basic devices for each laboratory, and most of the malfunctions that occur due to lack of experience in maintaining the device, lack of interest in it, and failure to maintain it. We found through our research that some analysts and engineers do not have sufficient knowledge to deal with these devices,so we wrote this research to be a simple and easy guide for them. To be their assistant to deal with these devices

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Technical development and future outlook for this research

1. Publish this research to be a general guide for recent graduates of the Department of Medical Engineering and Medical Laboratories, so that dealing with the aforementioned devices is easy and simple.
2. Writing other parts for several other types of devices such as diagnostic, radiological, dental and surgical devices.
3. Translating the research into several languages such as (Kurdish, Arabic, Turkmen, and English) to achieve maximum benefit from this research throughout Iraq.
4. Cooperating with specialized and experienced engineers to develop research and develop modern maintenance methods.

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