Sudan University of Science and Technology

College of Engineering

Department of Biomedical Engineering

Proposal of Standard Operation Procedure and Policies (SOPs) for Medical Imaging Instruments in Sudan

مقترح إجراءات التشغيل القياسية لاجهزة التصوير الطبي في السودان

(SOPs)

A project submitted in partial fulfillment to the requirements for the degree of B.Sc. in Biomedical Engineering

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ABSTRACT

Imaging devices are playing a big and important role in the diagnosis of the diseases. Unfortunately there are conflicting in the rules and regulations which were made by different organizations such as [national medicines and poisons board(NMPB), Sudanese standards and metrology organization(SSMO), Sudan Atomic Energy commission(SAEC) and medical supplies(MS)] to control the import and operation of these devices.

The multiplicity of organizations in this matter are Causing many problems that's make the standardized procedures lack in Sudan.

The aim of this work is to make an attempt unification of technical and operational measures for medical imaging devices in the Department of Radiology, improve the quality of service diagnostic of the disease and make written procedures followed by the staff to perform the job properly, ensure quality, prevent risks and mistakes, improve errors and reduce the costs.

In The first step in this work to reach that aims we followed operating procedures as it described in the operating manual of the devices. Secondly we determined the technical specifications of the device corresponding on the international specification such as The Food and **Drug** Administration FDA, Common Era CE, and International Organization for Standardization ISO.

In the Third step we wrote the procedures of the Safety (Electrical and radiation). Fourthly we determined the environmental conditions of the devices which were required. at the last step we tagged that there were a simple contamination (bacterial) in these devices and we provided how to avoid it.

After these steps we have been making a format to verify the experimental results which were obtained to know if the international standards are applying in the hospitals of Sudan.

The results showed that recently began attention occurring for the Imaging devices after returning to the manufacturer to make sure that they get on the after-sales service, spare parts and basic safeguards, in accordance with the principles and controls which were put by the different organizations in Sudan including making an impact on the provision of service desired.

It also found that the safety measures (electric and radiation) for these devices are followed accurately and knowledge of how to make safety tests which are not available to the staff.

This work is a beginning step to improve the use of imaging devices to ensure that we get the desired results better.

المستخلص

تلعب الاجهزة التصويرية دور كبير ومهم في تشخيص الامراض ولكن هنالك تضارب كبير فى الاسس والضوابط التى تحكم استيراد وتشغيل هذه الاجهزه وذلك لتعدد الجهات المعنية بهذا الامر (اداره الصيدلة والهيئة السودانية للمواصفات والمقايس وهيئة الطاقة الذرية والامدادت الطبية) مما تسبب في مشاكل كثيره وسبب عدم وجود اجراءات موحده مطبقه في السودان

الهدف من البحث محاوله توحيد الاجراءات التقنية والتشغيلية لاجهزة التصوير الطبي في قسم الاشعة وتحسين نوعية الخدمة التشخيصية للمرض ولعمل اجراءات مكتوبة يتبعها الموظفون لاداء الوظيفة بالصورة الصحيحة ولضمان الجودة ومنع المخاطر والاخطاء وتحسين الخطاء وخفض التكاليف

في هذا المقترح اتبعنا خطوات معينة للوصول الى تلك الاهداف وقد كانت الخطوة الاولى اتباع اجراءات التشغيل العملية كما موضحة في كتيب التشغيل للاجهزة . ثانيا تحديد المواصفات التقنية للجهاز . ثالثا السلامة (الكهربية و الاشعاعية) . رابعا تحديد الظروف البيئية المطلوبة . واخيرا التلوث (البكتيري) البسيط في هذه الاجهزة وكيفية تفاديه . بعد اجراء هذه الخطوات تم عمل فورمات للتحقق من النتائج التجريبية المتحصل عليها ومعرفة مدى استخدامها في عدد من المستشفيات .

بينت النتائج انه بدأ مؤخرا الاهتمام باستجلاب الاجهزة التصويرية بعد الرجوع الى الشركة المصنعة للتأكد من الحصول على خدمات ما بعد البيع وقطع الغيار و الضمانات الاساسية وذلك وفقا لأسس وضوابط موضوعة من عدة جهات لا يوجد تنسيق كافي بينها مما اثر على توفير الخدمة المنشودة . كما وجد ايضا ان اجراءات السلامة (الكهربائية و الاشعاعية) لهذه الاجهزة غير متبعة بصورة دقيقة وان الالمام بكيفية اجراء اختبارات السلامة غير متوفر لدى طاقم الموظفين .

هذا العمل هو خطوة البداية لتحسين استخدام الاجهزة التصويرية لضمان الحصول على النتائج المطلوبة بصورة افضل .

Chapter One
Introduction

1.1 Project Introduction

Physiological systems are very complex and hierarchical in structure and the complexity is present in every level including the organs, the cells and biochemical molecules. The great complexity of physiological systems makes it difficult to describe , interpret or explain their behavior without the assistance of some form of model. Simulations and modeling in respiratory medicine offer a number of opportunities. First, models and simulations can give us better understanding of the pathophysiology of disease processes. For example, constructing a multi-unit lung model with different regional ventilation and perfusion properties can help us understand gas exchange disturbances .Second, simulations and models are powerful educational tools. Observing a simulator or model's response to various manipulations can help educate health care professionals in diagnosis and treatment decisions Indeed, a wrong decision on an education simulator leads only to clinician learning, not to a real patient disaster .Education simulators can also be used for clinician testing and licensing. Third, a simulator or model can help predict a patient's response to planned therapies. For example, a mechanical lung model may be able to predict how a patient's respiratory system will respond to a change in a ventilator setting. Fourth, a computerized anatomic model of the respiratory system can be used to diagnose anatomic lesions and guide bronchoscopy and other invasive techniques. Fifth, simulators and models help assess and improve existing and new ventilation devices, technique and modes .

Approaches to modeling or simulating the respiratory system have taken many forms over the years ,as recognized through the works , for example, Douglas and Haldane (1908) and Horgan and Lange (1963).
The basic principle of hybrid modeling is that an existing numerical model is modified inserting in some of its parts, according to the specific needs, a physical model.

1.2 Problem Statement

Calibration of equipment need standard methods and specific tools to ensure the accuracy of the readings and the results obtained. These tools must be met for each device in order to be calibrated. In Sudan, most likely do not have these tools, which affects the process of diagnosis and treatment of these devices such as ventilator , which are the calibration process has improper, accordingly ,these tools must be available in order to be properly calibration process.

1.3 Objectives

1.3.1 General Objective

The aim of this work is to introduce hybrid model of respiratory system and understanding how it work. which enables connecting the real clinical devices with the computerized virtual lungs.

1.3.2 Specific Objectives

The main purpose of this work are:

1- to create tool for the calibration of the artificial ventilation equipment such as ventilator to find out the performance.
2- to educate and train of medical staff.
3- to develop the methods of modeling respiratory system and also assist ventilation.

1.4 Project organization

This project is divided into six chapters and is organized as follows:
In chapter one , discuss the introduction of simulation and modeling of respiratory system , problem statement , then general and specific objectives , and project organization , after that in chapter two describes the anatomy and physiology of respiratory system ,and modeling of respiratory system , then in chapter three reviews models of respiratory system , then in chapter four discuss the method of designing of hybrid model (software and hardware model), then in chapter five show results and discussion , then in chapter six suggest recommendation to implement in the future and conclusion. .