



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 لأجهزة التصوير الطبي في السودان

(SOPs)

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

Prepared by:

Najwa Farouq Saleh

Rawaa Emad Bdawi

Supervised by:

Dr. Mawia Ahmed Hassan

TABLE OF CONTENT

CHAPTER 1 INTRODUCTION	Error! Bookmark not defined.
1.1 Project introduction.....	Error! Bookmark not defined.
1.2 Project problem statement	Error! Bookmark not defined.
right step for Sudan.	Error! Bookmark not defined.
1.3 Thesis objectives.....	Error! Bookmark not defined.
1.4 Thesis organization	Error! Bookmark not defined.
CHAPTER 2.....	Error! Bookmark not defined.
2.1 X-RADIATION	Error! Bookmark not defined.
2.2 X-RAY MACHINE.....	Error! Bookmark not defined.
2.2.1 Mechanism	Error! Bookmark not defined.
2.2.2 Overview	Error! Bookmark not defined.
2.2.3 X-ray sources	Error! Bookmark not defined.
2.2.4 Detection	Error! Bookmark not defined.
2.2.5 Applications.....	Error! Bookmark not defined.
2.2.6 Medicine.....	Error! Bookmark not defined.
2.2.7 Security	Error! Bookmark not defined.
2.2.8 Advances in X-ray technology	Error! Bookmark not defined.
2.3 CT MACHINE	Error! Bookmark not defined.
2.3.1 Diagnostic use.....	Error! Bookmark not defined.
2.3.2 Advantages	Error! Bookmark not defined.
2.3.3 Adverse effects	Error! Bookmark not defined.
2.3.4 Dose vs. image quality	Error! Bookmark not defined.
2.3.5 Industrial use.....	Error! Bookmark not defined.
2.3.6 Types of machines	Error! Bookmark not defined.
2.4 Magnetic resonance imaging	Error! Bookmark not defined.
2.4.1 Introduction.....	Error! Bookmark not defined.
2.4.2 Neuroimaging	Error! Bookmark not defined.
2.4.3 Cardiovascular	Error! Bookmark not defined.
2.4.4 Musculoskeletal	Error! Bookmark not defined.

2.4.5 Liver and gastrointestinal MRI	Error! Bookmark not defined.
2.4.6 Functional MRI	Error! Bookmark not defined.
2.4.7 Oncology	Error! Bookmark not defined.
2.4.8 How MRI works.....	Error! Bookmark not defined.
2.4.9 Specialized applications.....	Error! Bookmark not defined.
2.5 The Ultrasound	Error! Bookmark not defined.
2.5.1 Description.....	Error! Bookmark not defined.
2.5.2 The components of the ultrasound machine:	Error! Bookmark not defined.
2.5.3 The Transducer:	Error! Bookmark not defined.
2.5.4 Modes of ultrasound (sonography):	Error! Bookmark not defined.
2.5.5 Procedures.....	Error! Bookmark not defined.
CHAPTER 3.....	Error! Bookmark not defined.
LITERATURE REVIEW	Error! Bookmark not defined.
3.1 SOUTH AFRICA	Error! Bookmark not defined.
3.2 KENYA.....	Error! Bookmark not defined.
3.3 EGYPT	Error! Bookmark not defined.
3.4 YEMEN.....	Error! Bookmark not defined.
3.5 BRAZIL	Error! Bookmark not defined.
3.6 United Arab Emirates.....	Error! Bookmark not defined.
CHAPTER 4 Methodology.....	Error! Bookmark not defined.
4.1 Introduction.....	Error! Bookmark not defined.
4.2 Operational requirement	Error! Bookmark not defined.
4.1 Technical Specification.....	Error! Bookmark not defined.
4.2 Safety	Error! Bookmark not defined.
4.3 Protective Earth Continuity.....	Error! Bookmark not defined.
4.4 High Voltage Test (Dielectric Voltage-withstand Test)	Error! Bookmark not defined.
4.5 Insulation Resistance Test	Error! Bookmark not defined.
4.6 Earth Bond Test	Error! Bookmark not defined.
4.7 Leakage Current Test (Line Leakage Test).....	Error! Bookmark not defined.
4.7.1 Acceptable Levels of Leakage Current	Error! Bookmark not defined.
4.7.2 Mains voltage on applied Parts.....	Error! Bookmark not defined.
4.7.3 Measuring Device.....	Error! Bookmark not defined.

4.7.4 Connection.....	Error! Bookmark not defined.
4.8 Electrical Safety Tests.....	Error! Bookmark not defined.
4.8.1 Radiation Safety.....	Error! Bookmark not defined.
4.8.2 Magnetic Resonance Imaging Safety	Error! Bookmark not defined.
4.8.3 X-ray Device Safety:	Error! Bookmark not defined.
4.8.4 The safety of the CT:	Error! Bookmark not defined.
4.8.5 Ultrasound SAFTY	Error! Bookmark not defined.
4.9 Environmental requirements	Error! Bookmark not defined.
4.9.1 Monitoring the environment.....	Error! Bookmark not defined.
4.10 Contamination	Error! Bookmark not defined.
CHAPTER 5.....	Error! Bookmark not defined.
5.1 Technical specification format:	Error! Bookmark not defined.
5.2 SAFETY FORMAT:	Error! Bookmark not defined.
5.3 ENVIROMENTAL FORMAT :	Error! Bookmark not defined.
5.4 Labling format:	Error! Bookmark not defined.
5.5 Experimental test:.....	Error! Bookmark not defined.
5.5.1 CT-Scanner	Error! Bookmark not defined.
5.5.2 THE Ultrasound.....	Error! Bookmark not defined.
5.5.3 X-RAY	Error! Bookmark not defined.
5.5.4 MRI	Error! Bookmark not defined.
5.6 SAFETY :.....	Error! Bookmark not defined.
CHAPTER 6.....	Error! Bookmark not defined.
6.1 CONCLUSION	Error! Bookmark not defined.
6.2 Future Work:	Error! Bookmark not defined.

TABLE OF FIGURES

Figure 2.1:GemX-160 - Portable Wireless Controlled Battery Powered X-ray	Error! Bookmark not defined.
Figure 2.2:Surgical mobiles can produce images continuously. .	Error! Bookmark not defined.
Figure 2.3:Hand-luggage inspection machine at Berlin Schönefeld Airport.	Error! Bookmark not defined.
Figure 2.4:dental digital X-ray system under testing in 2011	Error! Bookmark not defined.
Figure 2.5:Sketch of a CT scanner.....	Error! Bookmark not defined.
Figure 2.6:Picture of a CT scout (aka scanogram or topogram) as used for planning every scan slice.	Error! Bookmark not defined.
Figure 2.7:Computed tomography of human brain, from base of the skull to top. Taken with intravenous contrast medium.	Error! Bookmark not defined.
Figure 2.8:Example of a CTPA, demonstrating a saddle embolus (dark horizontal line) occluding the pulmonary arteries (bright white triangle)	Error! Bookmark not defined.
Figure 2.9:MRI image of white matter tracts.	Error! Bookmark not defined.
Figure 2.10:MR angiogram in congenital heart disease.....	Error! Bookmark not defined.
Figure 2.11:Medical MRI scanner	Error! Bookmark not defined.
Figure 2.12:DTI image.....	Error! Bookmark not defined.
Figure 2.13:Magnetic resonance angiography.....	Error! Bookmark not defined.
Figure 2.14:A fMRI scan showing regions of activation in orange, including the primary visual cortex (V1, BA17).	Error! Bookmark not defined.
Figure 2.15: The medical ultrasound machine.	Error! Bookmark not defined.
Figure 2.16:the main components of the ultrasound machine.	Error! Bookmark not defined.
Figure 2.17:Changing the shape of the surface of the probe and its size gives different images used for different applications.	Error! Bookmark not defined.
Figure 4.4.1: Current Test (Line Leakage Test).....	Error! Bookmark not defined.
Figure 4.2:Leakage Current Measurement Conditions.....	Error! Bookmark not defined.
Figure 4.3: Earth Leakage	Error! Bookmark not defined.
Figure 4.4: Enclosure Leakage.....	Error! Bookmark not defined.
Figure 4.5: Patient Leakage.....	Error! Bookmark not defined.
Figure 4.6: Patient auxiliary leakage current	Error! Bookmark not defined.
Figure 4.7: Mains voltage	Error! Bookmark not defined.
Figure 4.8: RADIATION	Error! Bookmark not defined.
Figure 4.9: Recommended "Snapshot" Monitoring Devices.....	Error! Bookmark not defined.
Figure 5.1 X-ray tube dual focus with capacity at least 3.5 MHU	Error! Bookmark not defined.
Figure 5.2 Have cooling rate not less than 700 KHU	Error! Bookmark not defined.
Figure 5.3 Detectores solid state/ceramic.....	Error! Bookmark not defined.
Figure 5.4 Detectores solid state/ceramic.....	Error! Bookmark not defined.
Figure 5.5 Have at least 650 per row of the effective elements/channels	Error! Bookmark not defined.
Figure 5.6 The gantry has a minimum tilt of 30 degrees	Error! Bookmark not defined.
Figure 5.7 The metal free scan at least 130 cms	Error! Bookmark not defined.
Figure 5.8 The metal free scan at least 130 cms	Error! Bookmark not defined.

- Figure 5.9 The minimum load bearing capacity of the patient table should be at least 200 kg **Error! Bookmark not defined.**
- Figure 5.10 The range of spiral facilities in axial direction more than 100 cms **Error! Bookmark not defined.**
- Figure 5.11 The screen is LCD and swiveling type..... **Error! Bookmark not defined.**
- Figure 5.12 Frequency of phase probe at the range **Error! Bookmark not defined.**
- Figure 5.13 Frequency of convex probe at the range **Error! Bookmark not defined.**
- Figure 5.14 Frequency linear array probe at the range..... **Error! Bookmark not defined.**
- Figure 5.15 Have A/B/M Modes..... **Error! Bookmark not defined.**
- Figure 5.16 Have a certificate CE , FDA..... **Error! Bookmark not defined.**
- Figure 5.17 Generators high frequency **Error! Bookmark not defined.**
- Figure 5.18 Type of tube : rotating anode **Error! Bookmark not defined.**
- Figure 5.19 Focal spot at least 1 mm..... **Error! Bookmark not defined.**
- Figure 5.20 Bucky grid type..... **Error! Bookmark not defined.**
- Figure 5.21 Have a certificate CE, FDA **Error! Bookmark not defined.**
- Figure 5.22 MRI Close Type..... **Error! Bookmark not defined.**
- Figure 5.23 Magnet field strength..... **Error! Bookmark not defined.**
- Figure 5.24 pass current onto the ground pin of a product **Error! Bookmark not defined.**
- Figure 5.25 Measure the voltage drop across the safety ground circuit to calculate the impedance of that circuit. **Error! Bookmark not defined.**
- Figure 5.26 Ensure probe is on a protectively earthed point. **Error! Bookmark not defined.**
- Figure 5.27 apply high voltage to the mains current carrying conductors (line and neutral) and the return path..... **Error! Bookmark not defined.**
- Figure 5.28 Measure the resulting leakage current **Error! Bookmark not defined.**
- Figure 5.29 Insulation test **Error! Bookmark not defined.**
- Figure 5.30 voltage test **Error! Bookmark not defined.**
- Figure 5.31 insulation resistance..... **Error! Bookmark not defined.**
- Figure 5.32 Move probe to find worst case..... **Error! Bookmark not defined.**
- Figure 5.33 line leakage test **Error! Bookmark not defined.**
- Figure 5.34 Run the device at rated voltage..... **Error! Bookmark not defined.**
- Figure 5.35 Measure the leakage current through resistive impedance **Error! Bookmark not defined.**

LIST OF TABLES

- Table 4.1 Technical specification for imaging devices..... **Error! Bookmark not defined.**
- Table 4.2: Leakage current limits summary **Error! Bookmark not defined.**
- Table 4.3: electrical safety **Error! Bookmark not defined.**
- Table 4.4: electrical safety test **Error! Bookmark not defined.**
- Table 4.5: The suitable standards for temperature and relative humidity for our devices are: **Error! Bookmark not defined.**
- Table 5.1: TECH SPEC FOR ULTRASOUND **Error! Bookmark not defined.**

Table 5.2: TECH SPECE FOR CT-SCAN	Error! Bookmark not defined.
Table 5.3:TECH SPEC FOR X-RAY	Error! Bookmark not defined.
Table 5.4: TECH SPECE FOR MRI.....	Error! Bookmark not defined.
Table 5.5: SAFETY FORMAT.....	Error! Bookmark not defined.
Table 5.6: TYPE OF LEACKAGE.....	Error! Bookmark not defined.
Table 5.7 X-ray Device Safety during operation.....	Error! Bookmark not defined.
Table 5.8 CT device safety during operation	Error! Bookmark not defined.
Table 5.9 Magnetic Resonance Imaging Safety.....	Error! Bookmark not defined.
Table 5.10 Ultrasound safety	Error! Bookmark not defined.
Table 5.11: ENVIROMENT FORMAT	Error! Bookmark not defined.
Table 5.12 labling format.....	Error! Bookmark not defined.

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 والمقاييس وهيئة الطاقة الذرية والامدادت الطبية) مما تسبب في مشاكل كثيرة وسبب عدم وجود اجراءات موحد مطبقه في السودان

الهدف من البحث محاوله توحيد الاجراءات التقنية والتنشغيلية لاجهزة التصوير الطبي في قسم الاشعة وتحسين نوعية الخدمة التشخيصية للمرض ولعمل اجراءات مكتوبة يتبعها الموظفون لاداء الوظيفة بالصورة الصحيحة ولضمان الجودة ومنع المخاطر والاطء 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 الامام 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. .