Sudan University of Science and Technology

College of Engineering

Department of Biomedical Engineering

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Basic Aspect for Specify the Medical Device

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Abbreviation

MRI	Magnetic Resonance Imaging
GHTF	*Global Harmonization Task Force*
ISO	International Standard Organization
IEC	International Electro-technical Commission
ANSI	American National Standards Institute
EN	European standard
DIN	Detaches Institute fur Norming
AAMI	Association for the Advancement of Medical Instrumentation
CSA	Canadian Standards Association
SCC	Standards Council of Canada
CEN	Comate European de Normalization
CENELEC	European Committee for Electro-technical Standardization
ETSI	European Telecommunication Standards Institute
ITU	International Telecommunication Union
ILAC	International Laboratory Accreditation Cooperation
FDA	Food and Drug Administration
ASTM	American Society for Testing and Materials
WHO	World Health Organization
LCD	Liquid-crystal Display
ICU	Intensive Care Unit
SpO2	Stands for Peripheral capillary oxygen
HR	Heart Rate
TFT	Thin-film-transistor
ECG	Electrocardiography

EC	European Commission

Abstract

Medical devices cover a variety of products designed to diagnose and treat patients. These devices range from a simple medical glove to a complicated Magnetic

Resonance Imaging machine (MRI). However different their composition may be, medical devices are all designed with the purpose of improving patient care.

The proportion of the rapid development and increasing complexities of electronics of medical devices, in addition to fact that 85% of medical dictions depend on a medical device, regulation and management of medical devices become most challenge term in healthcare process to ensure patient safety by identify risks and benefits of each medical device.

Lack and weakness of authority and lows which manage regulation process and procedures shows clearly in the third world countries (Sudan).

This research is an attempt to optimize medical devices regulation and control in Sudan by communion with the competent authority and highlight the shortcomings and their causes.

Also attempt to keep up the international standards and procedures applied in other develop countries and their organizations.

المستخلص

مصطلح الجهاز الطبي يستخدم لتعريف اجهزه و معدات مختلفه تختلف في درجة تعقيدها و مهامها و تتدرج من القفاز الطبي الى جهاز التصوير بالرنين المغنطيسي.و هي مع اختلافها الا ان الهدف منها هو ضمان التشخيص و العلاج الامن للمرضى.

نسبة للتطور الهائل في التكنولوجيا و زيادة التعقيد الالكتروني في الاجهزة الطبيه ،بالاضافه الى حقيقة ان 85% من القرارات الطبيه متخذه بواسطة الجهاز الطبي مما جعل عملية مراقبة و تنظيم هذه الاجهزة تمثل التحدي الاكبر في العمليه الصحيه لضمان سلامة المرضى بالتعريف بالمخاطر و الفوائد للجهاز الطبي.

قصور وضعف القوانين التي تحكم عملية تنظيم و مراقبة الاجهزة الطبيه و الاجراءات المتبعه يظهر بوضوح و يتعاظم في دول العالم الثالث و منها السودان.

هذا البحث محاوله لتحسين عملية تنظيم و مراقبة الاجهزة الطبيه في السودان بالتواصل مع جهات الاختصاص و تسليط الضوء على اوجه القصور و اسبابها.

ايضا محاولة لمواكبة المواصفات و الاجراءات العالميه المتبعه في دول متقدمه في هذا المجال و المنظمات التابعه لها.

CHAPTER ONE

INTRODUCTION

1.1. General view

Medical devices cover a variety of products designed to diagnose and treat Patients. These devices range from a simple medical glove to a complicated Magnetic Resonance Imaging machine (MRI). However different their composition may be, medical devices are all designed with the purpose of improving patient care.

In correlation with the demand for medical devices, there is a demand for thedevelopment of international standards that insure the safety and performance of the devices.

1.2. Problem Statement

Considering Sudan one of the Third World countries there is a lack of standard specifications of the Sudanese medical devices standards. These standards must develop to meet the international standards, which will insure safety and performance quality of medical devices before entering our country.

1.3. Objectives

1.3.1. General objectives

- Ensure patients safety is main objectives by identify and manage risks of medical devices.

- Economic objectives by reducing wasting money of malfunction which reduced after regulation process.

- Imposition particular national standards which mandate the manufactures to produce devices with specific standards pertaining to the work environment of the countries.

1.3.2. Specific objectives

1. Foundation of Sudanese approval system for medical devices.
2. Put down our national standards.
3. Founders specialist independent corporate responsible for regulation medical devices in country.
4. Ensure that all spare parts of device and maintenance available.
5. Study of standards and guidelines and recommendations for specification of medical devices in the Sudan.

6. Make mandatory standards controlled producer characteristics. For example the definition of terms and the dimensions of the device.

Thesis layout

This research includes seven chapters. Chapter one contains the general review, problems and objectives of the research. Theoretical fundamental was reviewed in chapter two. Chapter three contains background studies. Methodology was explained in chapter four. Chapter five includes results and analysis. Chapter six includes design and implementation**.** Chapter seven includes the discussion. Chapter eight includes recommendations and conclusions of the research. Chapter nine is references.