



Cairo University

# **ANALYSIS OF AUTOMATED EXTERNAL DEFIBRILLATOR FAILURES IN THE FDA MAUDE DATABASE**

By

**Eng. Amr Hashem Abu-Zaid Abdullah**

A Thesis Submitted to the  
Faculty of Engineering at Cairo University  
in Partial Fulfillment of the  
Requirement for the degree of  
**MASTER OF SCIENCE**  
in  
**BIOMEDICAL ENGINEERING AND SYSTEMS**

FACULTY OF ENGINEERING, CAIRO UNIVERSITY  
GIZA, EGYPT  
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Under the supervision of

**Prof. Dr. Bassel S. Tawfik**



Professor  
Department of Biomedical Engineering  
and Systems  
Faculty of Engineering, Cairo University

**Dr. Muhammad A. Rushdi**



Assistant Professor  
Department of Biomedical Engineering  
and Systems  
Faculty of Engineering, Cairo University

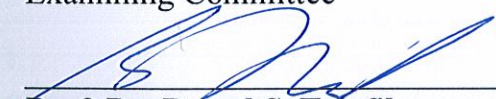
FACULTY OF ENGINEERING, CAIRO UNIVERSITY  
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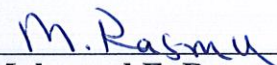
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Approved by the  
Examining Committee

  
**Prof. Dr. Bassel S. Tawfik,**

Thesis Main Advisor

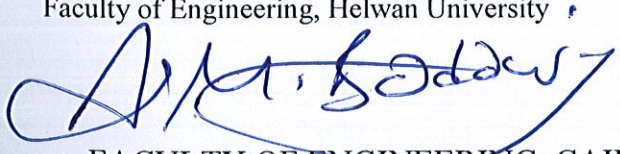
  
**Prof. Dr. Mohamed E. Rasmy,**

Internal Examiner

  
**Prof. Dr. Mohamed I. El-Adawy,**

External Examiner

- Department of Communication Engineering  
Faculty of Engineering, Helwan University

  
FACULTY OF ENGINEERING, CAIRO UNIVERSITY  
GIZA, EGYPT  
2013

**Engineer's Name:** Amr Hashem Abu-Zaid Abdullah  
**Date of Birth:** 17 / 02 / 1987  
**Nationality:** Egyptian  
**E-mail:** Amr.hashem.f@eng1.cu.edu.eg  
**Phone:** +201118266006  
**Address:** 3 st. Elshiekh Khattab – El Zaytoun – Cairo – Egypt.  
**Registration Date:** 1 / 10 / 2012  
**Awarding Date:** / /  
**Degree:** Master of Science  
**Department:** Biomedical Engineering and Systems



**Supervisors:** Prof. Dr. Bassel Tawfik  
Dr. Muhammad A. Rushdi

**Examiners:** Prof. Dr. Bassel S. Tawfik (Thesis main advisor)  
Prof. Dr. Muhammad E. Rasmy (Internal Examiner)  
Prof. Dr. Muhammad I. El-Adawi (External Examiner)  
(Department of Communication Engineering - Faculty of  
Engineering, Helwan University)

**Title of Thesis:**  
**Analysis of Automated External Defibrillator Failures in the FDA  
MAUDE Database**

**Key Words:**

Automated External defibrillator; Lithium-ion battery; Remaining useful life;  
Probability density function; Gaussian mixture model.

**Summary :**

Sudden cardiac arrest (SCA) is a leading cause of death worldwide. It is estimated that more than 3 million people die yearly. Early defibrillation using the automated external defibrillator (AED) has a key role in restoring normal heartbeat of a cardiac arrest patient. AED malfunction can convert the device from a life-saving to a life threatening device. According to FDA, automated external defibrillators (AEDs) are classified as Class-III high-risk medical devices. According to the FDA adverse event database, batteries are the most failure-prone AED components. Good estimation of AED battery life can help avoid AED adverse events, improve AED device reliability, and determine the minimum acceptable warranty period. Having a good battery management plan including a reasonable replacement time and a sufficient warranty period can easily lead to determine safely when the battery end-of-life is. Towards this end, we have investigated AED failure records reported to the FDA which obtained from the Manufacturer and User Facility Device Experience (MAUDE) database with the objective of finding out the best probability model to fit the data. Our results show that the generalized extreme-value probability distribution is the best-fit for the AED battery failure patterns.

# DISCLAIMER

I hereby declare that this thesis is my own original work and that no part of it has been submitted for a degree qualification at any other university or institute.

I further declare that I have appropriately acknowledged all sources used and have cited them in the references section.

Name: **Amr Hashem Abu-Zaid Abdullah**

Date:   /   /

Signature:

# **DEDICATION**

To my late aunt, Nagat Abu-Zaid, for her love and encouragement.

# ACKNOWLEDGMENTS

I would like to thank my advisers, Prof. Dr. Bassel S. Tawfik and Assistant Prof. Muhammad A. Rushdi, for their support and invaluable advice during various stages of the development of this dissertation.

Finally, I would like to express my gratitude to my wife, Zahra, for her understanding, endless patience and support over the years.

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# NOMENCLATURE

|                     |                                                            |
|---------------------|------------------------------------------------------------|
| AAMI                | Association for the Advancement of Medical Instrumentation |
| AED                 | Automated external defibrillator                           |
| AHA                 | American Health Association                                |
| AIC                 | Akaike information criterion                               |
| BIC                 | Bayesian information criterion                             |
| CDF                 | Cumulative distribution function                           |
| CPR                 | Cardiopulmonary resuscitation                              |
| DOD                 | Depth of discharge                                         |
| ECRI                | Emergency Care Research Institute                          |
| FDA                 | Food and Drug Administration                               |
| FMEA                | Failure mode and effects analysis                          |
| GEV                 | The generalized extreme value distribution                 |
| GMM                 | Gaussian mixture model                                     |
| ICD                 | Implantable cardio-verter defibrillator                    |
| Li-ion              | Lithium-ion battery                                        |
| Li-MnO <sub>2</sub> | Lithium-manganese dioxide battery                          |
| MAUDE               | Manufacturer and User Facility Device Experience database  |
| MDR                 | Medical device report                                      |
| MTBF                | Mean time between failure                                  |
| MTTF                | Mean time to failure                                       |
| PAD                 | Public access defibrillation                               |
| PDF                 | Probability density function                               |
| PMA                 | Pre-market approval                                        |
| RUL                 | Remaining useful life                                      |
| SCA                 | Sudden cardiac arrest                                      |
| SLA                 | Sealed lead acid battery                                   |
| TPLC                | Total product life cycle database                          |
| WHO                 | World Health Organization                                  |