Cairo University

ANALYSIS OF AUTOMATED EXTERNAL DEFIBRILLATOR FAILURES IN THR 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

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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.

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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_2	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