100/63/2015 DME 03/09

# DEVELOPMENT AND CLINICAL TESTING OF A NEGATIVE PRESSURE WOUND THERAPY DEVICE

Welgamage Pubudu Dilan Welgama

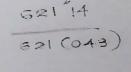
(09/8104)

Thesis submitted in partial fulfillment of the requirements for the degree

Master of Science by full time Research

Department of Mechanical Engineering

University of Moratuwa Sri Lanka





109006 TH2907

#### **DECLARATION**

I declare that this is my own work and this thesis does not incorporate without acknowledgement any material previously submitted for a Degree or Diploma in any other University or institute of higher learning and to the best of my knowledge and belief it does not contain any material previously published or written by another person expect where the acknowledgment is made in text.

Also, I hereby grant to University of Moratuwa the non-exclusive right to reproduce and distribute my thesis, in whole or in part in print, electronic or other medium. I retain the right to use this content in whole or part in future works (Such as articles or books)

UOM Verified Signature	18/12/2014
W.P.D. Welgama	Date

The above candidate has carried out research for the Masters Dissertation under my supervision.

UOM Verified Signature	18/12/2014	
Dr. H.A. Gray	Date	
UOM Verified Signature  Dr. Y.W.R. Amarasinghe	18/12/2014 Date	
UOM Verified Signature	Date	
Dr. A.G.T. Sugathapala	Date	

#### **ABSTRACT**

Negative Pressure Wound Therapy (NPWT) is a type of treatment in which suction is applied to a wound bed in combined with a specialized dressing to increase the wound healing rate. This study aims to develop a fully automated, portable and user friendly NPWT device and it is capable of increasing the healing rate of wounds, which cannot be healed by only using conventional wound treating methods. The pressure of the developed device can be controlled within the range of -25 mmHg to -250 mmHg with an accuracy of  $\pm$  3 mmHg. Pressure controlling is done by controlling rpm of the motor in the vacuum of the device. Dimensions of the developed device are 30 cm × 20 cm × 15cm, voltage is 12 V and power consumption range is 4 W to 10 W. The satisfactory level of user friendliness of the device was shown when it was being clinically tested by non-technical medical staff. To evaluate the performance of the device, it was clinically tested and validation was done by analyzing the clinical results. It was proved that this device has the same performance as previously validated NPWT devices, during the clinically testing. Reliability of the device was validated by longer period clinical testing at hospital. Portability, size reduction and possibility to operate using battery power supply are the other advantages of the device compared to other NPWT devices developed in Sri Lanka.

Keywords: NPWT, rpm, vacuum pump, clinical testing

This work is dedicated to my parents and my brother

This Research was supported by University of Moratuwa Senate Research
Grant Number SRC/LT/2010/01

#### **ACKNOWLEDGEMENTS**

Gaining a lot of experience form my masters degree, I would like to pay my gratitude to many people, supported me in different ways. Foremost, I should thank Dr. Hans Gray, the main supervisor of my research and the co-supervisors Dr. Ranjith Amarasinghe and Dr. Thusitha Sugathapala. Without their enthusiasm and motivation this research would not be a reality. Dr. Gray guided me in numerous ways in the research from his wealth of knowledge. He always encouraged me to achieve the goal when I encountered problems, especially, in the design stage. Dr. Amarasinghe is the person who inspired the research to be successful, sharing his valuable research experiences. He guided me to analyze the research outcome in different viewpoints. Without his guidance, the final research outcome and this thesis would not be a reality and I would sincerely like pay my uttermost gratitude to Dr. Amarasinghe. I would like to thank Dr. Sugathapala who shared his specialty knowledge in some stages, clarifying some theories.

I am very grateful to Dr. Ruwan Gopura who encouraged me to make this research a success and Professor Rahula Attalage for giving his support to overcome some problems during the period of research. Also I like to recall the support given by the Department of Mechanical Engineering, University of Moratuwa.

I would like to thank Professor Mandika Wijeratne who facilitated clinical testing at the General Hospital, Colombo (GHC) and for giving the background knowledge of medical aspects of the research. I should acknowledge Dr. Sushrutha Dissanayake and the medical staff of GHC for giving their support to carry out the clinical testing, successfully. The appreciation should also be gone to Dr. Thusitha Kahaduwa for providing the device developed by him, to take some important readings. I would also like to pay my sincere gratitude to Parker Hannifin Cooperation, USA and Mr. Udaya Amarasekara for their support given to succeed the research.

I greatly appreciate the support given by my colleagues, Gayan Sirimanna, Dulanjan Wijesinghe, Nalaka Samaraweera, Akalanka Jayakody, Upul Liyanarchchi and Chanaka Gunaratne of University of Moratuwa.

## TABLE OF CONTENTS

DECLARATION	i
ABSTRACT	ii
ACKNOWLEDGEMENTS	v
TABLE OF CONTENTS	vii
LIST OF FIGURES	x
LIST OF TABLES	xii
LIST OF ABBREVIATIONS	xiii
LIST OF APPENDICES	xiv
1 INTRODUCTION	1
1.1 Background	1
1.2 Current Study	2
1.3 Objectives of Current Study	2
1.4 Structure of the Thesis	2
2 LITERATURE REVIEW	4
2.1 Wounds	4
2.1.1 Types and Prevalence of Wounds	4
2.1.2 Wound Healing	4
2.2 Medical Background of NPWT	5
2.2.1 What is NPWT	5
2.2.2 History of NPWT	5
2.2.3 Proof and Clinical Study of NPWT	6
2.3 NPWT Systems	7
2.3.1 Current NPWT Systems	7
2.3.2 Locally Available NPWT Systems	8

	2.3.2.1 NPWT System Developed by GHC	8
	2.3.2.2 NPWT System Developed by DoME, UoM	. 10
	2.4 The Direction of the Current Study	. 12
	2.4.1 Flow of the NPWT Systems	. 13
	2.4.2 Available Pressure Controlling Methods for NPWT	. 13
	2.4.3 Vacuum Pumps	. 14
	2.4.4 Control System	. 17
	2.4.4.1 Pulse Width Modulation (PWM)	. 18
	2.4.4.2 DC Motor Controlling using PWM	. 18
	2.4.4.3 Main Controller	. 19
	2.4.5 Pressure Sensing	. 20
	2.4.6 Wound Dressings	. 20
3	DEVELOPMENT OF A NEW NPWT SYSTEM	. 22
	3.1 Component Identification	. 22
	3.2 Flow Measuring	. 22
	3.2.1 Flow Meter	. 22
	3.2.2 Flow Measuring of an Ankle Wound	. 24
	3.3 Pump Selection	. 24
	3.4 Control System	. 25
	3.4.1 Pressure Controlling	. 26
	3.4.2 Pressure Sensing	. 27
	3.4.3 User Machine Interface	. 28
	3.4.4 Selecting a Controller	. 28
	3.5 Final Design of the NPWT System	. 29
4	RESULTS AND DISCUSSION	. 32
	4.1 Main Results	. 32

	4.2	Clinical Test 1	37
	4.3	Clinical Test 2	43
	4.4	Clinical Performances of the NPWT system	44
	4.5	Physical Properties of the NPWT system	44
5	Con	clusions and Future Work	46
	5.1	Conclusions	46
	5.2	Future Work	47
R	EFERE	NCES	49
A	PPEND	IX A: Vacuum Pump Details	53
A	PPEND	IX B: Pressure Sensor Details	. 54
A	PPEND	IX C: Microcontroller Details	. 55
A	PPEND	IX D: Motor Controller Details	. 58

## LIST OF FIGURES

Figure 2. 1: (a) Horns used for hijamah (b) A traditional hajjam [17]	5
Figure 2. 2: (a) Rised using a blade (b) Liquid collecting to cups [17]	6
Figure 2. 4: Componets of a typical NPWT system	7
Figure 2. 5: Schematic diagram of NPWT system developed by GHC	9
Figure 2. 6: NPWT device developed by GHC	. 10
Figure 2. 7: Schematic diagram - NPWT system developed by DoME UoM	. 11
Figure 2. 8: NPWT device developed by DoME UoM	. 12
Figure 2. 9: Graph of converted DC pump	. 16
Figure 2. 10: Graph of converted AC pump	. 17
Figure 2. 11: Period and duty cycle	. 18
Figure 3. 1: Flow meter	. 22
Figure 3. 2: Pump characteristic curve	. 25
Figure 3. 3: NPWT system configuration	. 26
Figure 3. 4: Flow chart of the control system	. 30
Figure 3. 5: Developed NPWT system	. 30
Figure 3. 6: Compare the developed NPWT system with DoME device	.31
Figure 4. 1: Graph of pump and ankle wound leakage	. 32
Figure 4. 2: Graph of dressings of clinical test 1 and ankle wound leakages	. 34
Figure 4. 3: Graph of clinical test 2 and ankle wound leakages	. 36
Figure 4. 4: Initial stage of the wound of patient 1	. 37
Figure 4. 5: (a) Smith & Nephew intrasite gel (b) The gel applied on gauze.	. 38
Figure 4. 6: (a) Gauze layer 1 (b) Tube on layer 1 (c) Cover with layer 2	. 38
Figure 4. 7: NPWT dressing	. 39
Figure 4 8: NPWT device connected to a wound	39

Figure 4. 9: Collected liquids from wound after session 1 of clinical test 1	40
Figure 4. 10: Fluid collected from the wound at session 2, dressing 3	41
Figure 4. 11: One month after the NPWT therapy	42
Figure 4. 12: NPWT dressing fo clinical test 2	43
Figure 4. 13: Liquid collected from wound in clinical test 2	43
Figure 4. 14: Disposed canister and filter (a) clinical test 1 (b) clinical test 2.	45

## LIST OF TABLES

Table 2. 1: Commonly available vacuum pumps	. 16
Table 3. 1: Comparision of locally developed NPWT devices	. 31
Table 4. 1: Session 1 of clinical test 1 at General Hospital, Colombo	. 33
Table 4. 2: Session 2 of clinical test 1 at General Hospital, Colombo	. 33
Table 4. 3: Clinical test 2 at General Hospital, Colombo	.35

#### LIST OF ABBREVIATIONS

Abbreviation Description

DoME Department of Mechanical Engineering

FoM Faculty of Medicine

GHC General Hospital Colombo

NPWT Negative Pressure Wound Therapy

PIC Peripheral Interface Controller

PWM Pulse Width Modulation

RPM Revolutions Per Minute

UoM University of Moratuwa

## LIST OF APPENDICES

Appendix	Description	Page
Appendix A	Vacuum Pump Details	53
Appendix B	Pressure Sensor Details	54
Appendix C	Microcontroller Details	55
Appendix D	Motor Controller Details	58