

FUZZY LOGIC BASED MULTIMODALITY CLINICAL ALARM SYSTEM FOR
INTENSIVE CARE UNIT

SASIKALA DEVI THANGAVELU

A thesis submitted in fulfilment of the
requirements for the award of the degree of
Doctor of Philosophy

School of Biomedical Engineering and Health Sciences
Faculty of Engineering
Universiti Teknologi Malaysia

AUGUST 2022

DEDICATION

Dedicated to my beloved family Kalearasu, Shaman, Aishriah, Priyashya and most of all my parents Thangavelu Sockalingam and Kamalam Murugan.

ACKNOWLEDGEMENTS

Completion of this doctoral thesis was possible with the support of several people. I would like to express my sincere gratitude to all of them.

I am extremely grateful to Prof. Ir. Dr. Ing. Eko Supriyanto, Prof. Madya Ir. Dr. Azli Bin Yahya for their valuable guidance, scholarly inputs and consistent encouragement I received throughout the research.

This thesis would not have been possible without the help, support and patience of my supervisor, Prof. Ir. Dr. Ing. Eko Supriyanto not to mention his advice and unsurpassed knowledge. The good advice, support, and guidance of Dr. Muhammad Haikal Satria and Mohamad Haider Abu Yazid, have been invaluable for the completion of this research, for which I am extremely grateful.

I would like to acknowledge Y. Bhg. Datuk Seri Mohd Shafiq Abdullah, former Secretary General, Ministry of Health Malaysia, Y. Bhg. Tan Sri Dr Noor Hisham bin Abdullah, Director General of Health, Ministry of Health Malaysia, Y. Bhg. Datuk Zamane Abdul Rahman, Former Chief Executive of Medical Device Authority, Y. Bhg. Dato Dr. Zaininah binti Mohd Zain, Former Director of Hospital Kuala Lumpur, Y. Bhg. Datin Dr. Sivasakthi, Former Head of Department of Anesthesiology & Intensive Care, Hospital Kuala Lumpur, Dr. Tai Li Ling (Senior Consultant, Department of Anaesthesiology & Intensive Care, Hospital Kuala Lumpur) and staff of Main Intensive Care Unit, Hospital Kuala Lumpur and Hospital Sultanah Aminah Johor Baru for their contribution and support. I am extremely grateful to Dr. Tai Li Ling for her clinical expert advice, guidance, assistance, constructive comments, and feedback throughout the research. I am also thankful to Brig. Jen. Dato Dr. Jegathesan Singaraveloo and Dr. Krishant Kumar who patiently reviewed patient data for the research. My appreciation also goes to Arul Dass Michael and Paruvothy K.Veloo for assisting in data collection throughout the research.

I am indebted to my husband Kalearasu Veloo for his love, encouragement, and support throughout this study. I would also like to thank my family who has supported me in every possible way to see the completion of this work.

ABSTRACT

In high workload areas such as the Intensive Care Units (ICU), clinicians are burdened with too many alarms and false alarms, leading to alarm fatigue that causes poor user response or no response. The alarm fatigue issue has become a top patient safety hazard issue in healthcare institution. The current clinical alarms design lacks critical information, difficult to identify, distinguish, create confusions and lacks human factor engineering (HFE) principles. As such in this research, HFE principles and fuzzy logic techniques are identified to reduce user-related hazards and false alarm to improve clinicians' responses. Fuzzy logic techniques are the most frequently used Artificial Intelligence techniques to monitor the patient physiological condition, which requires a clinical decision based on vital sign information. Fuzzy logic has benefits over other algorithmic approaches, as it has the potential to incorporate values from ordinal, nominal and continuous datasets within its rules. The vital sign information to determine patients' risk or alarm conditions has been established, machine learning-based algorithms is unnecessary to train to classify patient risk . Fuzzy logic techniques were identified to diagnose alarm conditions and classify vital sign alarm signals based on risk. This research aims to develop a multimodality clinical alarm software based on HFE principles and artificial intelligence to improve user response and performance of alarm systems. Observation study, focus group, task analysis, simulation testing, and root cause analysis were conducted to identify the root cause of alarm hazards in ICU. The information such as patient condition, device condition, risk-based alarm classification and urgency mapping were identified to mitigate this alarm hazard. Based on this, a new earcon-based multimodality alarms were developed for technical and clinical alarm. A pilot study was conducted using a newly developed alarm simulator to test, verify and validate the new multimodality alarm. The findings identified 1250-1500Hz earcons and 2750-3000Hz earcons to represent medium and high priority clinical alarms respectively. Whereas a combination of sequence of earcons, 525Hz and 550Hz to represent technical alarms. The interburst interval of the alarm waveform (tb) of 5.0sec and 0.5sec for medium and high risk urgency mapping were identified. In this research, four vital sign alarms in patient monitor, Heart Rate (HR), Respiration (RESP), Noninvasive blood pressure (NIBP) and Oxygen Saturation (SPO2) were identified and developed as fuzzy logic based multimodality alarms. Fuzzy logic techniques were used classify these alarms as high risk, medium risk, and normal conditions. These alarms were tested using MIMIC II real patient data, compared and validated with the medical professional evaluation. The results indicated that the sensitivity and specificity of blood pressure and heart rate alarm algorithms are 100.00%. The sensitivity and specificity for respiratory alarm algorithm are at 97.59% and 99.68%, whereas sensitivity and specificity for oxygen saturation at 100.00% and 98.04% respectively. The research concluded that incorporating alarm information based on risk, human factor engineering principles, and fuzzy logic in the alarm system significantly reduce the number of false alarms, improves user response, reduce alarm hazards and improve patient safety in ICU.

ABSTRAK

Di kawasan beban kerja yang tinggi seperti Unit Rawatan Rapi (ICU), petugas klinikal dibebani dengan terlalu banyak penggera dan penggera palsu. Ini mengakibatkan 'keletihan pengera' yang menyebabkan respon pengguna yang lemah atau tiada respons. Isu 'keletihan penggera' menjadi isu utama membahayakan keselamatan pesakit di institusi kemudahan kesihatan. Rekabentuk penggera klinikal semasa kekurangan maklumat kritikal, sukar untuk dikenalpasti, dibezakan dan akibatkan kekeliruan serta kekurangan prinsip kejuruteraan faktor manusia (HFE). Dalam penyelidikan ini, prinsip HFE dan teknik fuzzy logic dikenalpasti untuk mengurangkan bahaya penggunaan dan memperbaiki respon petugas klinikal. Teknik fuzzy logic ialah teknik Kecerdasan Buatan (AI) yang paling kerap digunakan untuk memantau keadaan fisiologi pesakit yang memerlukan keputusan klinikal berdasarkan maklumat tanda vital. Fuzzy logic mempunyai faedah lebih berbanding kaedah algoritma yang lain kerana berpotensi untuk menggabungkan nilai set data ordinal, nominal dan berterusan dalam peraturannya. Maklumat tanda vital yang menentukan risiko telah pun wujud, algoritma berasaskan pembelajaran mesin lain adalah tidak perlu untuk melatih mengklasifikasikan risiko pesakit. Teknik fuzzy logic dikenalpasti untuk mendiagnosis keadaan penggera dan mengklasifikasikan isyarat penggera tanda vital berasaskan risiko. Penyelidikan ini bertujuan untuk membangunkan perisian penggera klinikal pelbagai mod berdasarkan prinsip HFE dan AI untuk memperbaiki respon pengguna dan prestasi sistem penggera. Kajian pemerhatian, kumpulan fokus, analisis tugas, ujian simulasi, dan analisis punca telah dijalankan untuk mengenalpasti punca bahaya penggera di ICU. Maklumat berkaitan keadaan pesakit, keadaan peranti, klasifikasi penggera berasaskan risiko dan pemetaan segera dikenalpasti untuk mengatasi bahaya penggera ini. Berdasarkan maklumat ini, isyarat penggera pelbagai mod berasaskan earcon dibangunkan untuk penggera teknikal dan klinikal. Kajian rintis dengan simulator penggera dijalankan untuk menguji, membandingkan dan mengesahkan penggera baru ini. Penemuan ini mengenalpasti 1250-1500Hz earcons dan 2750-3000Hz earcons masing-masing mewakili penggera klinikal berisiko sederhana dan tinggi. Manakala gabungan earcon, 525Hz dan 550Hz mewakili penggera teknikal berisiko tinggi dan sederhana. Penemuan ini juga mengenalpasti selang celah bentuk isyarat penggera (tb), 5.0 saat dan 0.5 saat untuk pemetaan berisiko sederhana dan tinggi. Empat penggera tanda vital dalam pemantau pesakit dikenalpasti dan dibangunkan sebagai penggera pelbagai mod berasaskan fuzzy logic, Kadar Jantung (HR), Pernafasan (RESP), Tekanan darah noninvasif (NIBP) dan Tepu Oksigen (SPO2). Teknik fuzzy logic mengklasifikasikan penggera ini sebagai risiko tinggi, risiko sederhana dan keadaan biasa. Penggera algoritma ini di uji dengan data pesakit sebenar MIMIC-II, dibandingkan dan disahkan dengan penilaian pengamal perubatan profesional. Keputusan menunjukkan sensitiviti dan kekhususan tekanan darah dan algoritma penggera kadar jantung adalah 100.00%. Sementara itu, kepekaan dan kekhususan bagi algoritma penggera kadar pernafasan dan ketepuan oksigen adalah masing-masing pada 97.59%, 99.68% dan 100.00%, 98.04%. Penyelidikan menyimpulkan bahawa menggabungkan sistem maklumat penggera berdasarkan risiko, prinsip HFE, dan fuzzy logic dalam sistem penggera dengan ketara mengurangkan penggera palsu, memperbaiki respon pengguna, mengurangkan bahaya penggera dan meningkatkan keselamatan pesakit di ICU.

TABLE OF CONTENTS

	TITLE	PAGE
	DECLARATION	iii
	DEDICATION	iv
	ACKNOWLEDGEMENTS	v
	ABSTRACT	vi
	ABSTRAK	vii
	TABLE OF CONTENTS	viii
	LIST OF TABLES	xiii
	LIST OF FIGURES	xvii
	LIST OF ABBREVIATIONS	xx
	LIST OF APPENDICES	xxi
CHAPTER 1	INTRODUCTION	1
	1.1 Overview	1
	1.2 Problem Background	4
	1.3 Research Questions	6
	1.4 Research Aim	6
	1.5 Research Objectives	7
	1.6 Scope of Study	7
	1.7 Significance of Study	9
	1.8 Thesis Outline	9
CHAPTER 2	LITERATURE REVIEW	11
	2.1 Introduction	11
	2.2 Alarm System and Standards	12
	2.3 Alarm System Design	14
	2.4 Problems Associated with Clinical Alarm System	18
	2.5 Auditory Signal for Clinical Alarm	26
	2.6 Urgency Mapping	30

2.7	Psychoacoustic and Psychophysical Effects of Alarm Sound	32
2.8	Visual Display	34
2.9	IEC62366:2007: Usability Testing (Human Factors Testing)	36
2.10	Artificial Intelligence	38
	2.10.1 Artificial Intelligence in Medical Alarms	39
	2.10.2 Comparative Study on Application of Artificial Intelligence in Medical Devices	40
	2.10.3 Fuzzy Logic	44
2.11	Discussion and Summary	51
CHAPTER 3	RESEARCH METHODOLOGY	55
3.1	Introduction	55
3.2	Research General Framework	55
3.3	Part 1: Research Planning	63
3.4	Part 2: Root Cause Analysis of Clinical Alarm Hazard Based on HF Studies	63
	3.4.1 Observational Study	64
	3.4.2 Simulation and Testing of Current Alarm Sounds from Medical Devices in ICU	67
	3.4.3 Focus Group (FG)	68
	3.4.4 Task Analysis	70
	3.4.5 Root Cause Analysis (RCA)	72
	3.4.6 Alarm Information Model (AIM)	76
	3.4.6.1 AIM Development	76
3.5	Part 3: Development of Fuzzy Based Multimodality Clinical Alarm Model	82
	3.5.1 Development of Alarm Simulator Model (ASM)	83
	3.5.1.1 Identification of Features and Functionality of Alarm Simulator	84
	3.5.1.2 Design and Development of the 4 Vital Sign Alarm Simulator	92
	3.5.2 Development of Multimodality Clinical Alarm	96

3.5.2.1	Development and Identification of New Clinical and Technical Alarm Based on Earcons	100
3.5.2.2	Development of Visual Alarm	102
3.5.2.3	Comparative Study Between New Multimodality Alarm Signal and Current Alarm Signal	103
3.5.3	Pilot Study: Simulation Test for Multimodality Clinical Alarm System Using ASM	104
3.5.4	Development of Fuzzy Based Multimodality Clinical Alarm Model	104
3.5.4.1	Blood Pressure Alarms Modality	109
3.5.4.2	Heart Rate Alarms Modality	116
3.5.4.3	Respiratory Rate Alarms Modality	121
3.5.4.4	Oxygen Saturation (SpO2) Alarms Modality	127
3.5.4.5	Functionality Test	133
3.5.4.6	Real Patient Data (Mimic Data base)	135
3.5.4.7	Evaluation of Patient Data by Expert	136
3.5.4.8	Fuzzy Based Multimodality Clinical Alarm Simulations	137
3.6	Final Design and Discussion	140
CHAPTER 4	RESULTS AND DISCUSSION	143
4.1	Introduction	143
4.2	Findings of Observational Study	144
4.3	Findings of the Existing Alarm in Medical Devices Placed in ICU/CCU	144
4.4	Findings of Focus Group (FG)	148
4.5	Findings of Task Analysis	149
4.5.1	Outcome of Task 1	150
4.5.2	Outcome of Task 2	152
4.5.3	Discussion	157
4.6	Findings of Root Cause Analysis (RCA)	161
4.6.1	Discussion	166

4.7	Findings of Alarm Information Model	167
4.7.1	Discussion	168
4.7.1.1	Information 1: Device and Patient Specific: Auditory Alarm	168
4.7.1.2	Information 2: Patient Status: Visual Alarm	169
4.7.1.3	Information 3: Technical Alarm	172
4.7.1.4	Information 4; Auditory Alarm; Alarm Condition and the Associate Risk To The Patient or the Device Condition.	173
4.7.1.5	Information 5: Auditory Alarm: Response Time Urgency Coding	174
4.8	Findings of Alarm Simulator Model (ASM) Based On AIM	175
4.8.1	Features and Functionality of ASM	176
4.8.2	ASM Operation	177
4.8.3	Findings of Visual Alarm Display	179
4.8.4	Classification of Vital Sign Measurement for ASM	181
4.9	Findings of the Multimodality Clinical Alarm	182
4.9.1	Finding of New Technical Audio Alarms	182
4.9.2	Finding of New Clinical Alarm Signal	186
4.10	Pilot Test - Findings	189
4.11	Findings of Fuzzy Based Multimodality Clinical Alarm	194
4.11.1	Findings Based on Alarm Functionality Test	194
4.11.2	Findings Based on Alarm Functionality Test Results	195
4.11.3	Evaluation of Patient Data by Expert	196
4.12	Summary and Discussion	199
CHAPTER 5	CONCLUSION AND RECOMMENDATIONS	203
5.1	Research Outcomes	203
5.2	Contributions To Knowledge	205
5.3	Limitations of the Current Work and Suggestions	209
5.4	Suggestions for Future Work	210

REFERENCES	213
APPENDICES	221
LIST OF PUBLICATIONS	311

LIST OF TABLES

TABLE NO.	TITLE	PAGE
Table 1.1	Summary of research objectives and corresponding scope of study	8
Table 2.1	Limitation of alarm system based on IEC standard	13
Table 2.2	Recommendations to alarm philosophy	15
Table 2.3	Recommendations to alarm design	16
Table 2.4	Comparison of previous research implementation of neural network and fuzzy logic in medical alarm	42
Table 2.5A	Comparison of previous research implementation of machine learning in medical alarm	43
Table 2.6	The data input for fuzzy logic system in this research	46
Table 2.7	Alarms according to patient vital signs conditions	48
Table 3.1	RCA action plan tool template	74
Table 3.2	Extract from to IEC 60601-1-8: 2006: “Table 201 – Alarm Condition Priorities”	79
Table 3.3	Characteristics of Alarm Indicator Lights;(IEC60601-1-8:2006)	80
Table 3.4	NEWS2 clinical risk	81
Table 3.5	Alarm signal based on standard and proposed specification	81
Table 3.6	Basic Modules in the physiological monitor	85
Table 3.7	Summarized PM-ASM requirements	91
Table 3.8	AIM model: Auditory alarm signal design specification	98
Table 3.9	Alarm signal based on standard and proposed specification	101
Table 3.10	Characteristics of Alarm Indicator Lights;(IEC60601-1-8:2006)	102
Table 3.11	Classification of physiological measurement	106
Table 3.12	Input/ Output table for Multimodality clinical alarm algorithms	109
Table 3.13	Physiological risk measurement for blood pressure	110

Table 3.14	Physiological risk measurement for blood pressure	110
Table 3.15	Input membership class setup for blood pressure	110
Table 3.16	Output membership class setup for blood pressure	111
Table 3.17	Output membership class setup for blood pressure	113
Table 3.18	Fuzzy rules for blood pressure	115
Table 3.19	Physiological risk measurement for heart rate	116
Table 3.20	Physiological risk measurement for heart rate	116
Table 3.21	Input membership class setup for heartrate	117
Table 3.22	Output membership class setup for Heartrate	118
Table 3.23	Fuzzy rules for heart rate	121
Table 3.24	Physiological risk measurement for respiratory rate	121
Table 3.25	Physiological risk measurement for respiratory rate	122
Table 3.26	Input membership class setup for respiratory rate	122
Table 3.27	Output membership class setup for respiratory rate alarm	124
Table 3.28	Input membership class setup for respiratory rate	126
Table 3.29	Fuzzy rules for respiratory rate	127
Table 3.30	Physiological risk measurement for SpO2	127
Table 3.31	Input membership function for SpO2	128
Table 3.32	Output membership class setup for SPO2	129
Table 3.33	Fuzzy rules for SPO2	133
Table 3.34	Physiological Measurement upper and lower limits	134
Table 3.35	Patient Vital Sign Table Evaluated by Medical Expert	137
Table 3.36	Performance evaluation description	138
Table 3.37	Performance evaluation for Multimodality clinical alarm	139
Table 4.1	Percentage of occurrence of false alarm among medical devices in ICU	144
Table 4.2	Demography of the respondents WP4	145
Table 4.3	One sample proportion test result for device recognition	146
Table 4.4	One-sample proportion test results for risk recognition	147
Table 4.5	Focus Group-1 findings	148

Table 4.6	Outcome of task analysis	158
Table 4.7	Task analysis recommendation	160
Table 4.8	RCA1 of alarm incidents due to user response	162
Table 4.9	Prioritised Contributing Factors to prevent incident	164
Table 4.10	AIM model: Auditory alarm signal design specification	167
Table 4.11	NEWS2 clinical risk	170
Table 4.12	Extract from To IEC 60601-1-8: 2006: “Table 201 – Alarm Condition Priorities”	173
Table 4.13	Characteristics of Alarm Indicator Lights;(IEC60601-1-8:2006)	174
Table 4.14	Physiological measurement upper and lower limits	177
Table 4.15	AIM design information	178
Table 4.16	Vital Sign (physiological) measurement upper and lower limits	181
Table 4.17	Medium risk technical alarm	182
Table 4.18	Selection of medium risk technical alarm (Sample A and E)	183
Table 4.19	Selection of high risk technical alarm (Sample B, C and D)	184
Table 4.20	Urgency mapping for high-risk technical alarm	184
Table 4.21	Urgency mapping for Medium Priority Technical (alarm sample E)	185
Table 4.22	Demography	186
Table 4.23	New auditory Earcon clinical alarm signal	187
Table 4.24	New medium risk AIM1 alarm signal; interburst interval (tb)	188
Table 4.25	New high risk auditory Earcon alarm signal; interburst interval (tb)	188
Table 4.26	Alarm signal based on standard IEC compared with new alarm design signals	189
Table 4.27	Demography of pilot test	190
Table 4.28	Medium and high priority clinical auditory alarm (20 respondents)	190
Table 4.29	Learnability and urgency identification of NIBP/SPO2/HR/RESP (20 respondents)	191
Table 4.30	Physiological measurement upper and lower limits	194

Table 4.31	Patient vital sign table evaluated by medical expert	196
Table 4.32	The performance of proposed fuzzy alarm for blood pressure	197
Table 4.33	The performance of proposed fuzzy alarm for heart rate	197
Table 4.34	The performance of proposed fuzzy alarm for respiratory rate	198
Table 4.35	The performance of proposed fuzzy alarm for oxygen saturation	198
Table 4.36	Proposed fuzzy alarm accuracy	199

LIST OF FIGURES

FIGURE NO.	TITLE	PAGE
Figure 2.1	Flow chart adapted from on human-interface machine (Redmill and Jane Rajan, 1997)	24
Figure 2.2	Basic Fuzzy System Configuration (Gafa, 2020)	44
Figure 2.3	The examples of commonly used membership function for fuzzy logic system	46
Figure 2.4	Defuzzification examples using Mamdani	50
Figure 3.1	Research Flowchart	57
Figure 3.2	General research framework	62
Figure 3.3	Observation study flowchart	66
Figure 3.4	Focus group flowchart	69
Figure 3.5	The five steps and opportunities to incorporate human factors as part of ^{HF} RCA	72
Figure 3.6	ASM development flowchart	84
Figure 3.7	The four colour coded quadrants of PM:ASM Display	89
Figure 3.8	Block diagram for BP	93
Figure 3.9	Block diagram for heart rate	94
Figure 3.10	Block diagram for respiratory rate	95
Figure 3.11	Block diagram for oxygen saturation	96
Figure 3.12	Fuzzy based Multimodality clinical alarm model	105
Figure 3.13	Input Membership function examples for oxygen saturation	108
Figure 3.14	Output membership for oxygen saturations alarm	108
Figure 3.15	High risk 1 membership function for blood pressure alarm	111
Figure 3.16	Medium risk and normal membership function for blood pressure alarm	112
Figure 3.17	High risk 2 membership function for blood pressure alarm	112
Figure 3.18	Output membership function for blood pressure alarm	113

Figure 3.19	Input membership function for blood pressure alarms as shown in fuzzy logic designer in MATLAB	114
Figure 3.20	Output membership function for blood pressure alarms as shown in fuzzy logic designer in MATLAB	114
Figure 3.21	High risk 1 membership function for heart rate alarm	117
Figure 3.22	Medium risk and normal membership function for heart rate alarm	117
Figure 3.23	High risk 2 membership function for heart rate alarm	118
Figure 3.24	Output membership function for heart rate alarm	119
Figure 3.25	Input membership function for heart rate alarms	119
Figure 3.26	Output membership function for Heart Rate Alarms	120
Figure 3.27	High risk 1 membership function for respiratory rate alarm	122
Figure 3.28	Medium risk and normal membership function for respiratory rate alarm	123
Figure 3.29	High risk 2 membership function for respiratory rate alarm	123
Figure 3.30	Output membership function for respiratory rate alarm	124
Figure 3.31	Input membership function for respiratory rate alarms	125
Figure 3.32	Output membership function for respiratory rate alarms	125
Figure 3.33	High Risk Membership Function for SpO2Alarm	128
Figure 3.34	Medium risk function for SpO2 alarm	128
Figure 3.35	Normal membership function for SpO2 alarm	129
Figure 3.36	Output membership function for SpO2 alarm	130
Figure 3.37	Input membership function for SpO2 alarms	131
Figure 3.38	Output membership function for SpO2 alarms	132
Figure 3.39	Examples of confusion matrix	139
Figure 4.1	Task1 Admission of patient in ICU	151
Figure 4.2	Task 1 Process flow diagram for admission of patient in ICU	151
Figure 4.3	Task II: Monitoring of patient and alarm response	154
Figure 4.4	Task II: Process flow diagram for alarm monitoring and responding in ICU	157
Figure 4.5	Ishikawa Fish Bone Diagram	164

Figure 4.6	NEWS thresholds and triggers	171
Figure 4.7	The NEWS scoring system	172
Figure 4.8	The four quadrants of ASM model	176
Figure 4.9	The four quadrants of ASM model	180
Figure 4.10	The ASM display with visual colour coded alarms	180
Figure 4.11	Proposed multimodality clinical alarm signal for ASM as patient monitor	193
Figure 4.12	The ASM display with visual colour coded alarms	193
Figure 4.13	Alarm functionality test on a. heart rate, b. respiratory rate, c. blood pressure and d. oxygen saturation	195

LIST OF ABBREVIATIONS

IEC	-	International Electrotechnical Commission
ICU/CCU	-	Intensive Care Unit/Critical Care Unit
ECRI	-	Emergency Care Research Institute
ACCE	-	American College of Clinical Engineers
CDRH	-	Center for Devices and Radiological Health
FG	-	Focus group
AAMI	-	Association for the Advancement of Medical Instrumentation
ANSI	-	American National Standards Institute
GMDN	-	Global Medical devices Nomenclature
FDA	-	Food and Drug Administration
FDA-MAUDE	-	Food and Drug Administration-Manufacturer and user facility device
HF	-	Human Factors
HFE	-	Human Factors Engineering
ECG	-	Electrocardiogram
HR	-	Heart rate
SPO2	-	Oxygen saturation
NIBP	-	Non Invasive Blood Pressure
RESP	-	Respiration
API	-	Application Programming Interface
NMRR	-	National Medical Research Register
MOH	-	Ministry of Health, Malaysia
MFTP	-	Multivariable fuzzy temporal profile
WP	-	Workprogram
RR	-	Respiration Rate
ME	-	Medical Equipment
UE	-	Usability Engineering
OR	-	Operation Room

LIST OF APPENDICES

APPENDIX	TITLE	PAGE
Appendix A	Research Registration Details	221
Appendix B	Observational Study	222
Appendix C	9 Step Planning Guide for Focus Group	228
Appendix D	Workprogram WP2: Focus Group FG2	230
Appendix E	Workprogram WP2: Focus Group FG3	235
Appendix F	Workprogram WP2: Focus Group FG4	242
Appendix G	Workprogram WP2: Focus Group FG5	247
Appendix H	Workprogram WP3: Testing of Current Alarm Sound in ICU	255
Appendix I	Workprogram WP4: Task Analysis on The Problems Associated With Alarm System	258
Appendix J	Workprogram WP5: Root Cause Analysis (RCA)	266
Appendix K	Workprogram WP6: Basic Modules in The Physiological Monitor	272
Appendix L	orkprogram WP7: Designing New Earcon Auditory Alarm Signal Based on IEC 60601-1-8:2006	273
Appendix M	Workprogram WP8: Pilot Study -Simulation Testing of Multimodality Alarm With ASM	287
Appendix N	Calibration Procedure	291
Appendix O	Medical Professionals Evaluation for Patients Physiology	292
Appendix P	Confusion Matrix for Simulated Fuzzy Alarm for Patient Data	302

CHAPTER 1

INTRODUCTION

1.1 Overview

Most medical devices are incorporated with alarm systems to alert clinicians of patient conditions and malfunction of the device. A well-designed alarm system will trigger alarms when there are abnormal changes in physiological conditions of the patient or the device itself, act as a decision aid to improve clinician's task performance and patient safety. Conversely, a poorly designed system may cause irritation or distraction to the clinicians, impede performance and cause poor response leading to patient hazards.

The patient monitoring device monitors the patient's vital parameters and gives the first pronouncement of patient conditions. In high workload areas such as clinical intensive care, the hospital is surrounded by these devices, therapeutic and other diagnostic devices. The combination of these devices is closed-loop controlled for patient safety under the surveillance of clinicians. Here, medical device alarms continuously monitor the physiological condition of the patients. As a result, the clinician in this high workload area is burdened with too many alarms, primarily ineffective alarms, and false-positive leading to poor user response or no response to the alarm signal, which in turn leads to alarm hazards and serious patient safety concerns.

When there are true alarms, false recognition, wrong action, or even switching off the alarms by the clinician could lead to catastrophic patient outcomes, leading to injury or death. In addition, the multitude of alerts from device alarms can cause alarm fatigue among clinicians leading to unnecessary hazard that can compromise the quality and safety of patient care.

A further problem arises as to the device from different brands and types giving different alarm signals for the same patient conditions and similar alarm signals for different patient conditions.

In critical care, the high occurrence of false alarms is the main problem with the clinical alarm system and main cause of alarm adverse events (Bach, Berglund and Turk, 2018a). Studies have indicated that 80-99% of the alarms are false alarms (Fernandes, Miles, De Lucena and Cowan, 2020; Fernandes, Miles, De Lucena and Cowan, 2019). This problem is further stressed in the review papers, which highlight problems of the high occurrence of false alarms, which have no clinical significance and are perceived as a hindrance in safety monitoring by the medical staff (Özcan and Gommers, 2020; Sowan, Staggers, Berndt, Austin, Reed, Malshe, Kilger, Fonseca, Vera and Chen 2021). The high rates of false alarms have also shown to cause alarm fatigue among clinicians which have led to degrade the performance of human-device interface system, clinical alarm system response and desensitization to alarms compromising the quality and safety of patient care (Fernandes et al., 2020; Ruppel, De Vaux , Cooper , Kunz , Duller and Funk, 2018; Fernandes. et al., 2019). Research has also suggested that people will decrease their response as the false alarm rate increases (Fernandes et al., 2019).

Clinical alarm hazards warrant the greatest attention as they continue to be a serious patient safety concern and are reported to be the top health technology hazard in healthcare institutions for ten consecutive years between 2010 and 2020 (ECRI, 2019). The clinical alarm hazards have led to numerous adverse events leading to injury and death. As such, there is a need to mitigate and resolve problems emanating from alarm hazards and poor user response and ensure patient safety. The effectiveness of alarms requires the inclusion of the latest technology, best clinical practices, and device capabilities based on Human Factor Engineering (HFE) principles to ensure the effectiveness of the alarm signals (Özcan et al., 2020; Bogner, 1999; Bach et al., 2018b; Schlesinger et al., 2018).

Several researchers have proposed the use of artificial intelligence or machine learning for the use of the medical alarm. Artificial intelligence can be embedded to

assist in decision-making, monitoring, and medical diagnosis (Fernandes et al., 2020; Au-Yeung, Sahani, Isselbacher and Armoundas, 2019; Fernandes et al., 2019; Li, Meng, Su and Kwok, 2018; Utekar and Umale, 2018; Rekha, Shashank, Rakshith, Ranganna and Sunag et al., 2020). (Au-Yeung et al. (2019) has highlighted the application of artificial intelligence in intensive care monitoring. Artificial intelligence based fuzzy logic could mimic clinician decision making ability and power the progress of analytics in healthcare applications (Al-Dmour, Sagahyroon, Al-Ali and Abusnanaet, 2019). AL based on fuzzy classifiers has been used to detect abnormalities in healthcare monitoring (Li et al., 2018). Fuzzy-based pre-diagnosis monitoring was used in another study to patient monitoring and categorise patients' status (Al-Dmour et al., 2019). A similar study on monitoring vital signs in ICU was conducted using the fuzzy mode to classify vital signs (Li et al., 2018). AI could be used in the classification of true alarm and false alarm in multi-signal vital sign monitoring or bedside patient monitoring (Fernandes et al., 2020). The classification is limited between real and artifact data based on BP, RR, NIBP, and SpO2. Among those signals, the difference in prediction is uncertainty between the true alert and artifact uncertainty. The differentiation signals in each vital sign alert condition could help improve the classification method.

There is a lack of integrated alarm research that combines HR-based auditory, visual alarms, risk-based alarms, and fuzzy-based alarm detection to improve user response and performance of alarms in ICU/CCU. The proposed research based on fuzzy logic was used to identify a method to classify true alarms and categorize them as medium and high-risk. The vital signs were also analysed and classified by a physician and compared with fuzzy classification to determine the accuracy. The fuzzy logic was proposed in this research because the fuzzy rules are easily programmed and have shown the potential to execute repetitive tasks and mimic human reasoning in a complex environment such as ICU/CCU (Shanmugham, Strawderman, Babski-Reeves and Bianet, 2018; Fernandes et al., 2019).

1.2 Problem Background

The FDA-MAUDE database reported 112 deaths and 1281 injuries related to alarm systems between 2010 to 2020 (USFDA, 2020). The report indicated that the clinical alarm hazard led to adverse events related to the audible alarm, caused 86.6% of death, and 80.5% injuries. FDA has also reported 216 monitor alarm-related deaths from January 2005 to June 2010. These numerous adverse events have led alarm hazard to be issued as top ten health technology hazards between 2010-2020 (ECRI, 2010-2020). Since 2013-2020, Joint Commission (JC) has published alarm safety as one of the ten goals of the National Patient Safety Goal (Joint Commission, 2020). These unresolved alarm hazard problems need to be investigated to identify the root cause and determine strategies to minimise the occurrence of these problems.

Numerous studies have suggested that there is gap between the alarm standard, IEC60601-1-8 and how it is applied in the alarms design in the ICU/CCU that has multiple medical devices (Bach et al., 2018a). The review by Bach et al. also indicated that alarms based on this standards are difficult to identify and distinguish, with persistent confusions between alarm system from different manufacturer (Bach et al., 2018a). As such, there is a limitation in the current alarm system designed based on this standard, leading to poor user response and alarm hazard. Therefore, there is a need to investigate limitations of these alarms system based on human factor and integrate with new technology such as AI to improve effectiveness of the alarm system in medical devices.

Studies have indicated a high occurrence of false alarms in critical care (Sowan et al., 2021; Walsh and Waugh, 2020). The high rates of false alarms indicate that the alarms are unreliable, leading the clinicians not to respond and, at times to switch off the alarm (Fernandes et al., 2020; Özcan et al., 2020; Ruppel et al., 2018). These present a potentially serious patient safety issue especially in ICU where the patients are critically ill and ‘true positive alarm’ could be ignored. As such there is a need to identify the root cause of false alarm and propose latest AI technologies to identify true alarms, ensuring effectiveness of the alarm system and enhancing patient safety.

The high alarm rates are known to a major concern for the patient safety and largest contributing factor alarm related adverse events (Walsh et al., 2020). The phenomenon of alarm fatigue is due to too many alarms resulting in clinicians being overwhelmed and desensitized to alarms. The alarm fatigue issue has become a top patient safety hazard issue in healthcare institution. Alarm fatigue has led to lack of response, including a delayed response, disabling alarms, turning the volume to inaudible, or adjusting alarms' settings to hazardous limits, which can result in serious patient safety issue (Shanmugham et al., 2018; Fernandes et al., 2020). The severity of this problem has become a major patient safety concern (Özcan et al., 2020). Numerous studies has been conducted to improve alarm fatigue in ICU such as changes in default alarm settings, application of AI based on automatic reasoning system, machine learning, intelligent patient monitoring and alarm system based on fuzzy logic, applications of fuzzy model for processing and monitoring vital signs in ICU patients (Sowan et al., 2021; Özcan et al., 2020; Shanmugham et al., 2018; Fernandes et al., 2019; Au-Yeung et al., 2019; Bach et al., 2018a). There are gaps in the research, and root cause of this hazard needs to be analysed; mitigating strategies have been identified based on AI to reduce the false alarm and improve user response as well as to enhance patient safety.

In high workload environment such as ICU, high stress levels and risk conditions shall increase risk of user errors or incidents which could lead to severe complication or fatality. Therefore, there is a need to mitigate this user risk by designing clinical alarms based on HF to reduce user- related hazards and improve clinicians' responses (Özcan et al., 2020). Further, to reduce the high occurrence of false alarms and reduce alarm fatigue in ICU/CCU, there is a need to integrate default alarm setting with fuzzy logic-based alarm classification system (Al-Dmour et al., 2019).

Hence, this research is motivated by the need to identify the root cause of alarm hazards and mitigate problems that cause alarm hazards to improve patient safety. The research focuses on HF-based alarm signals and fuzzy logic-based multimodality clinical alarm to improve the effectiveness of the alarm and user response in ICU/CCU.

1.3 Research Questions

The research questions are identified to address and focus on the central research problem in the research area of study, the performance of the medical devices alarm system in ICU/CCU. This research seeks to answer the following research questions. There is a need to identify the problems associated with the clinical alarm system that led to false or unnecessary alarms that could affect patient safety in healthcare institutions. There is a need to identify the root cause of alarm problems in ICU/CCU and how to mitigate these issues in the alarm design. The alarms should assist the clinician in monitoring the physiological condition, and as such human factor engineering principles need to be identified and applied in the alarm design. The problems related to alarm response need to be identified and addressed to reduce alarm hazards to ensure patient safety. New multimodality alarms comprising auditory and visual need to be identified and developed based on HF to improve the alarm performance in ICU/CCU. Further, the methodology for improving the alarm response based on HF has to be identified to assist the clinician in responding promptly and in a timely manner.

The methodologies to reduce the false alarms and reduce alarm fatigue in ICU/CCU have to be identified and addressed in the alarm design. There is a need to study the application of artificial intelligence to improve the performance of clinical alarms system. Numerous studies have been done on applying fuzzy logic techniques to monitor the patient in ICU/CCU. As such, there is a need to study and identify the fuzzy logic techniques to reduce false alarms in ICU/CCU. The fuzzy logic algorithm and the testing techniques have to be identified, developed and validated to ensure the accuracy, sensitivity and specificity of the fuzzy logic-based alarms.

1.4 Research Aim

The research aim of the study summarizes the research area, methodology and outcome of the research study. Based on the research questions, this research aims to incorporate multimodality clinical alarm systems based on auditory and visual clinical

alarms systems and incorporate artificial intelligence for alarm classification in the clinical alarm signal in ICU to improve the response and performance of alarm systems to ensure patient safety.

1.5 Research Objectives

This study's research objectives are formulated to address how to achieve the research aims. Based on the background information and research questions, the research objectives will facilitate the achievement of the study's aims. The first objective is to identify and produce a root cause analysis of the clinical alarm hazard in the healthcare institution. The second objective is to formulate a new fuzzy logic-based multimodality clinical alarm system by incorporating human factor engineering principles for the clinical alarms system. Finally, to analyse and validate the fuzzy-based multimodality clinical alarm system in patient monitor clinical setting.

1.6 Scope of Study

This research focusses on clinical alarm system software simulation based on Audacity software, MIMIC 11 data and MATLAB with inclusion of critical technical alarms built in medical devices and used in healthcare institution. The scope of the research according to the objective is listed in the following Table 1.1.

Table 1.1 Summary of research objectives and corresponding scope of study

Objective	Scope of Study
(a) To identify and produce root cause analysis of the clinical alarm hazard in the healthcare institution	(a) The problems associated with the clinical alarm system in intensive care unit
	(b) Performance of existing alarm system at ICU/CCU
	(c) The application of human factor engineering in the design considerations for clinical alarms in ICU/CCU?
(b) To develop a new fuzzy logic-based multimodality clinical alarm system by incorporating human factor engineering principles for the clinical alarms system	(d) Patient monitoring alarms
	(e) Alarm classification in patient monitoring
	(f) Multimodality clinical alarms, acoustic and visual alarm of the clinical alarm system
	(g) Application of multimodality clinical alarm in monitor patient monitor medical devices to monitor Heart Rate (HR), Non-invasive Blood Pressure (NIBP), Arterial Oxygen Saturation (SPO2) and respiration (RESP)
	(h) Develop alarm simulator for simulating real time vital sign
	(i) Focus on fuzzy logic to improve alarm performance
	(j) Integration of new alarm system with existing medical devices in the ICU and Medical Device Standard (IEC 60601-1-8 & IEC 62366)
(c) To analyse and validate the fuzzy based multimodality clinical alarm system in patient monitor clinical setting.	(k) clinical alarm system software simulation based on Audacity software, MIMIC 11 data and MATLAB

1.7 Significance of Study

This research proposed a fuzzy logic base multimodality clinical alarm monitor software to improve alarm response among the clinicians in ICU/CCU and the performance of the clinical alarm. This led to several contributions and significance to the study of clinical alarm systems in ICU/CCU. In this research, root cause analysis of the clinical alarm hazard in healthcare institution led to identification the problems of alarm system design, psychoacoustic principles of alarm sound, improvement of the standard and alarm information model (AIM)

The outcome of the HF studies led to the development of a new multimodality clinical alarm based on AIM with new risk-based alarm classification, earcon-auditory with a visual alarm, NEWS-based patient representation, and urgency mapping to improve the response of the alarm system in ICU/CCU.

A new Alarm simulator was developed based on AIM to mimic patient monitor and trigger vital sign alarms such as Heart Rate (HR), Noninvasive Blood Pressure (NIBP), and Arterial Oxygen Saturation (SPO2) and respiration (RESP). This simulator was used to verify the new multimodality alarms and upgraded as a web-based alarm monitor for remotely monitoring vital sign.

The significance of this study includes formulating a New fuzzy-based multimodality clinical alarm to reduce false alarms and improve the performance of alarm systems in medical devices in ICU/CCU. The new method of expert validation of the fuzzy-based multimodality clinical alarm gives the significance to the study.

1.8 Thesis Outline

This thesis consists of 5 chapters. Chapter 1 provides the study's introduction, problem background and statement, aim, objectives, the scope of the studies and the significance of this research. Chapter 2 discuss the literature review of the related literature on clinical alarm systems, associated problems, human factor principles in

alarm design and the application of fuzzy logic in alarm design. Finally, it reviews and critically evaluates the available research on alarm systems to synthesize, reveal limitations, identify gaps and establish new perspectives for the main contributions of the research.

Chapter 3 describes the research methodology used to achieve all the objectives in this research. These include HF methodologies such as observational study, task analysis, root cause analysis and the development of an alarm information model (AIM). It also includes designing and developing an alarm simulator model (ASM), multimodality clinical alarm signal, pilot study and integration of fuzzy logic in the multimodality clinical alarm signal. Chapter 4 discuss the results and analysis of the outcome of the study. This chapter discusses verifying and validating the fuzzy-based multimodality clinical alarm model. Chapter 5 details the conclusion of the thesis, the limitation, and recommendations for future research on the alarm system. The Significance of this study includes formulating a New fuzzy-based multimodality clinical alarm to reduce false alarms and improve the performance of alarm systems in medical devices in ICU/CCU. The new method of expert validation of the fuzzy-based multimodality clinical alarm gives the significance to the study.

REFERENCES

- ACCE (2007) 'Impact of clinical alarms on patient safety: A report from the American College of Clinical Engineering Healthcare Technology Foundation', *Journal of Clinical Engineering*, pp. 22–33.
- Akira, S. P., Claudia, S., Lina, M., Monique, S., Weber-Carstens, S., Henning, K. and Felix, B. (2018) 'Clinical requirements of future patient monitoring in the ICU : A qualitative', (December).
- Al-Dmour, J. A., Sagahyroon, A., Al-Ali, A. R. and Abusnana, S. (2019) 'A fuzzy logic-based warning system for patients classification', *Health Informatics Journal*, 25(3), pp. 1004–1024.
- Amer, A. Y. A., Vranken, J., Wouters, F., Mesotten, D., Vandervoort, P., Storms, V., Luca, S., Vanrumste, B. and Aerts, J. M. (2019) 'Feature engineering for ICU mortality prediction based on hourly to bi-hourly measurements', *Applied Sciences (Switzerland)*, 9(17), pp. 1–17.
- Amer, A. Y. A., Wouters, F., Vranken, J., Dreesen, P., Boer, D. de K. de, Rosmalen, F. van, van Bussel, B. C. T., Smit-Fun, V., Duflot, P., Guiot, J., van der Horst, I. C. C., Mesotten, D., Vandervoort, P., Aerts, J. M. and Vanrumste, B. (2021) 'Vital signs prediction for covid-19 patients in icu', *Sensors*, 21(23), pp. 1–15.
- Amer, A. Y. A., Wouters, F., Vranken, J., de Korte-De Boer, D., Smit-Fun, V., Duflot, P., Beaupain, M. H., Vandervoort, P., Luca, S., Aerts, J. M. and Vanrumste, B. (2020) 'Vital signs prediction and early warning score calculation based on continuous monitoring of hospitalised patients using wearable technology', *Sensors (Switzerland)*, 20(22), pp. 1–21.
- Au-Yeung, W.-T. M., Sahani, A. K., Isselbacher, E. M. and Armoundas, A. A. (2019) 'Reduction of false alarms in the intensive care unit using an optimized machine learning based approach', *npj Digital Medicine*. Springer Science and Business Media LLC, 2(1).
- Bach, T. A., Berglund, L.-M. and Turk, E. (2018a) 'Managing alarm systems for quality and safety in the hospital setting', *BMJ Open Quality*, 7(3), p. e000202.

- Bach, T. A., Berglund, L.-M. and Turk, E. (2018b) 'Managing alarm systems for quality and safety in the hospital setting', *BMJ Open Quality*. BMJ, 7(3), p. e000202.
- Becker, K., Kasmacher, H., Rau, G., Kalff, G. and Zimmermann, H. J. (1994) 'Fuzzy logic approach to intelligent alarms in cardioanesthesia', *IEEE International Conference on Fuzzy Systems*, 3, pp. 2072–2076.
- Bliss, J. P. and Dunn, M. C. (2000) 'Behavioural implications of alarm mistrust as a function of task workload', *Ergonomics*, pp. 1283–1300. doi: 10.1080/001401300421743.
- Catchpole, K. R., McKeown, J. D. and Withington, D. J. (2004) 'Localizable auditory warning pulses', *Ergonomics*, pp. 748–771.
- Chambrin, M. C. (2001) 'Alarms in the intensive care unit: How can the number of false alarms be reduced?', *Critical Care*, 5(4), pp. 184–188.
- Chambrin, M. C., Jaborska, A., Boniface, B., Chopin, C., Calvelo-Aros, D. and Ravaux, P. (1999) 'Multicentric study of monitoring alarms in the adult intensive care unit (ICU): a descriptive analysis', *Intensive Care Medicine*, pp. 1360–6.
- 'Chart 2 : NEWS thresholds and triggers' (no date), p. 2017.
- Cobus, V. and Heuten, W. (2019) 'To beep or not to beep? Evaluating modalities for multimodal ICU alarms', *Multimodal Technologies and Interaction*. MDPI AG, 3(1), pp. 1–29.
- Cretikos, M. A., Bellomo, R., Hillman, K., Chen, J., Finfer, S. and Flabouris, A. (2008) 'Respiratory rate: The neglected vital sign', *Medical Journal of Australia*.
- Drews, F. A. (2008) *Patient Monitors in Critical Care: Lessons for Improvement, Advances in Patient Safety: New Directions and Alternative Approaches (Vol. 3: Performance and Tools)*.
- Dumas, J. S. and Janice C, R. (1999) *A Practical Guide to Usability Testing*.
- Dutta, S., Maeder, A. and Basilakis, J. (2013) 'Using fuzzy logic for decision support in vital signs monitoring', *CEUR Workshop Proceedings*, 1098(2002), pp. 29–33.
- ECRI (2010) *Top 10 Technology Hazards for 2010*.
- Edworthy, J. (2011) 'Designing effective alarm sounds', *Biomedical Instrumentation and Technology*, 45(4), pp. 290–294.

- Edworthy, J. (2013) 'Medical audible alarms: A review', *Journal of the American Medical Informatics Association*, 20(3), pp. 584–589.
- Edworthy, J. and Hellier, E. (2005) 'Fewer but better auditory alarms will improve patient safety', *Quality and Safety in Health Care*, 14(3), pp. 212–215.
- Edworthy, J. and Hellier, E. (2006) 'Alarms and human behaviour: Implications for medical alarms', *British Journal of Anaesthesia*. *British Journal of Anaesthesia*, 97(1), pp. 12–17.
- Edworthy, J., Hellier, E., Titchener, K., Naweed, A. and Roels, R. (2011) 'Heterogeneity in auditory alarm sets makes them easier to learn', *International Journal of Industrial Ergonomics*, 41(2), pp. 136–146.
- Edworthy, J. and Meredith, C. S. (1994) 'Cognitive psychology and the design of alarm sounds', *Medical Engineering and Physics*, 16(6), pp. 445–449.
- Edworthy, Judy, Reid, S., Mcdougall, S., Edworthy, Jonathan, Hall, S., Bennett, D., Khan, J. and Pye, E. (2017) 'The recognizability and localizability of auditory alarms: setting global medical device standards', *Human Factors*.
- Elliott, M. and Coventry, A. (2012) 'Critical care: The eight vital signs of patient monitoring', *British Journal of Nursing*.
- Felix, S., Goepfert, M. and Reuter, D. A. (2013) 'patient monitoring alarms in ICU and in the operating room', *Critical Care*.
- Fernandes, C., Miles, S. and Lucena, C. J. P. (2020) 'Detecting false alarms by analyzing alarm-context information: Algorithm development and validation', *JMIR Medical Informatics*.
- Fernandes, C. O., Miles, S., De Lucena, C. J. P. and Cowan, D. (2019) 'Artificial intelligence technologies for coping with alarm fatigue in hospital environments because of sensory overload: Algorithm development and validation', *Journal of Medical Internet Research*. *Journal of Medical Internet Research*, 21(11).
- Gafa, C. (2020) *A very brief introduction to Fuzzy Logic and Fuzzy Systems*.
- Guillaume, A. (2011) 'Intelligent auditory alarms', in *The Sonification Handbook*, pp. 493–508.
- Hellier, E. J., Edworthy, J. and Dennis, I. (1993) 'Improving auditory warning design: Quantifying and predicting the effects of different warning parameters on perceived urgency', *Human Factors*, pp. 693–706.
- IEC Standard (2006) *MS IEC60601-1:2006*.

- Ieronutti, L., Ranon, R. and Chittaro, L. (2005) 'Human-Computer Interaction - INTERACT 2005', *Lecture Notes in Computer Science (including subseries Lecture Notes in Artificial Intelligence and Lecture Notes in Bioinformatics)*, 3585(May 2014), pp. 873–885.
- Imhoff, M. and Kuhls, S. (2006) 'Alarm algorithms in critical monitoring', *Anesthesia and Analgesia*, 102(5), pp. 1525–1537.
- Joint Commission (2020) *National Patient Safety Goals*.
- Jones, K. (2014) 'Alarm fatigue a top patient safety hazard.', *CMAJ: Canadian Medical Association journal = journal de l'Association medicale canadienne*, p. 178. doi: 10.1503/cmaj.109-4696.
- Kristiani, D. G., Triwiyanto, T., Nugraha, P. C., Irianto, B. G., Syaifudin and Titisari, D. (2019) 'The Measuring of Vital Signs Using Internet of Things Technology (Heart Rate and Respiration)', in *Proceedings - 2019 International Seminar on Application for Technology of Information and Communication: Industry 4.0: Retrospect, Prospect, and Challenges, iSemantic 2019*.
- Lacherez, P., Seah, E. L. and Sanderson, P. (2007) 'Overlapping melodic alarms are almost indiscriminable', *Human Factors*, 49(4), pp. 637–645.
- Leite, C. R. M., Sizilio, G. R. A., Neto, A. D. D., Valentim, R. A. M. and Guerreiro, A. M. G. (2011) 'A fuzzy model for processing and monitoring vital signs in ICU patients', *BioMedical Engineering Online*.
- Li, W., Meng, W., Su, C. and Kwok, L. F. (2018) 'Towards false alarm reduction using fuzzy if-Then rules for medical cyber physical systems', *IEEE Access*. IEEE, 6, pp. 6530–6539.
- Loeb, R. G. and Fitch, W. T. (2002) 'A Laboratory Evaluation of an Auditory Display Designed to Enhance Intraoperative Monitoring', *Anesthesia & Analgesia*, 94(2), pp. 362–368.
- Malhotra, S., Laxmisan, A., Keselman, A., Zhang, J. and Patel, V. L. (2005) 'Designing the design phase of critical care devices: A cognitive approach', *Journal of Biomedical Informatics*, 38(1), pp. 34–50.
- Mamdani, E. H. H. and Assilian, S. (1975) 'An experiment in linguistic synthesis with a fuzzy logic controller. International journal of man-machine studies', *International Journal of Man-Machine Studies*.

- Mondor, T. A. and Finley, G. A. (2003) 'The perceived urgency of auditory warning alarms used in the hospital operating room is inappropriate', *Canadian Journal of Anesthesia*, 50(3), pp. 221–228.
- Morey, A. and Penelope, S. (2005) 'Testing New Alarms for Medical Electrical Equipment', in, pp. 12–16.
- Oberli, C., Urzua, J., Saez, C., Guarini, M., Cipriano, A., Garayar, B., Lema, G., Canessa, R., Sacco, C. and Irrarrazaval, M. (1999) 'An expert system for monitor alarm integration', *Journal of Clinical Monitoring and Computing*, pp. 29–35.
- Orr, J. A. and Westenskow, D. R. (1994) 'A breathing circuit alarm system based on neural networks', *Journal of Clinical Monitoring*, 10(2), pp. 101–109.
- Özcan, E. and Gommers, D. (2020) 'Nine Nurse-Recommended Design Strategies to Improve Alarm Management in the ICU: A Qualitative Study', *ICU Management & Practice*, 20(2), pp. 129–133.
- Patterson, R. D. (1990) 'Auditory warning sounds in the work environment.', *Philosophical transactions of the Royal Society of London. Series B, Biological sciences*, 327(1241), pp. 485–492.
- Penelope , Alexandra Wee, Eunice Seah, and P. L. (2006) 'AUDITORY ALARMS , MEDICAL STANDARDS , AND URGENCY Penelope Sanderson , Alexandra Wee , Eunice Seah , and Philippe Lacherez Key Centre for Human Factors and School of ITEE The University of Queensland , St Lucia , Australia', (July), pp. 24–27.
- Penelope, S., Alexandra, W., Eunice, S. and Philippe, L. (2006) 'AUDITORY ALARMS , MEDICAL STANDARDS , AND URGENCY Penelope Sanderson , Alexandra Wee , Eunice Seah , and Philippe Lacherez Key Centre for Human Factors and School of ITEE The University of Queensland , St Lucia , Australia', in *12th International Conference on Auditory Display, London, UK*, pp. 24–27.
- Phillips, J. A. (2006) 'Clinical Alarms: Complexity and Common Sense', *Critical Care Nursing Clinics of North America*.
- Physicians, R. C. of (2017) 'Clinical response to NEWS trigger thresholds', *National Early Warning Signs*, p. 2017.
- Princy, S. and Dhenakaran, S. S. (2016) 'Comparison of Triangular and Trapezoidal Fuzzy Membership Function', *Journal of Computer Science and Engineering*.

- Rangkuti, A. H. and Rasjid, Z. E. (2014) 'The detection of 4 vital signs of in-patients Using fuzzy database', *EPJ Web of Conferences*, 68.
- Redmill, F. and Jane Rajan (1997) 'Human factors in safety-critical systems', *Journal of Hazardous Materials*, p. 218.
- Rekha, K. S., Shashank, S., Rakshith, M. C., Ranganna, S. S. and Sunag, T. P. (2020) 'A novel framework for monitoring the remotely located patients using an iot based healthcare system', in *11th International Conference on Advances in Computing, Control, and Telecommunication Technologies, ACT 2020*.
- Royal College of Physicians (2017a) 'Chart 1 : The NEWS scoring system', *Royal College of Physicians*, p. 2017.
- Royal College of Physicians (2017b) 'National Early Warning Score (NEWS) 2. Standardising the assessment of acute-illness severity in the NHS Updated report of a working party Executive summary and recommendations', (December), pp. 1–15.
- Ruppel, H., De Vaux, L., Cooper, D., Kunz, S., Duller, B. and Funk, M. (2018) 'Testing physiologic monitor alarm customization software to reduce alarm rates and improve nurses' experience of alarms in a medical intensive care unit', *PLoS ONE*, 13(10), pp. 1–16.
- Sadollah, A. (2018) 'Introductory Chapter: Which Membership Function is Appropriate in Fuzzy System?', in *Fuzzy Logic Based in Optimization Methods and Control Systems and its Applications*.
- Sanderson, P. M., Liu, D. and Jenkins, S. A. (2009) 'Auditory displays in anesthesiology', *Current Opinion in Anesthesiology*, 22(6).
- Sanderson, P. M., Wee, A. and Lacherez, P. (2006) 'Learnability and discriminability of melodic medical equipment alarms', *Anaesthesia*, 61(2), pp. 142–147.
- Sari, W. E., Wahyunggoro, O. and Fauziati, S. (2016) 'A comparative study on fuzzy Mamdani-Sugeno-Tsukamoto for the childhood tuberculosis diagnosis', in *AIP Conference Proceedings*.
- Schuh, C. J. (2008) 'Monitoring the fuzziness of human vital parameters', in *Annual Conference of the North American Fuzzy Information Processing Society - NAFIPS*.
- Seccareccia, F., Pannojo, F., Dima, F., Minoprio, A., Menditto, A., Noce, C. L. and Giampaoli, S. (2001) 'Heart rate as a predictor of mortality: The MATISS project', *American Journal of Public Health*.

- Shanmugham, M., Strawderman, L., Babski-Reeves, K. and Bian, L. (2018) 'Alarm-Related Workload in Default and Modified Alarm Settings and the Relationship Between Alarm Workload, Alarm Response Rate, and Care Provider Experience: Quantification and Comparison Study', *JMIR Human Factors*, 5(4), p. e11704.
- Siebig, S. *et al.* (2010) 'Intensive care unit alarms-How many do we need?', *Critical Care Medicine*. doi: 10.1097/CCM.0b013e3181cb0888.
- Sowan, A. K., Gomez, T. M., Tarriela, A. F., Reed, C. C. and Paper, B. M. (2016) 'Changes in default alarm settings and standard in-service are insufficient to improve alarm fatigue in an intensive care unit: A pilot project', *JMIR Human Factors*.
- Sowan, A. K. and Reed, C. C. (2017) 'A complex phenomenon in complex adaptive health care systems - Alarm fatigue', *JAMA Pediatrics*.
- Sowan, A. K., Stagers, N., Berndt, A., Austin, T., Reed, C. C., Malshe, A., Kilger, M., Fonseca, E., Vera, A. and Chen, Q. (2021) 'Improving the Safety, Effectiveness, and Efficiency of Clinical Alarm Systems: Simulation-Based Usability Testing of Physiologic Monitors', *JMIR Nursing*, 4(1), p. e20584.
- Subbe, C. P., Davies, R. G., Williams, E., Rutherford, P. and Gemmell, L. (2003) 'Effect of introducing the Modified Early Warning score on clinical outcomes, cardio-pulmonary arrests and intensive care utilisation in acute medical admissions', *Anaesthesia*.
- Tsien, C. L. and Fackler, J. C. (1997) 'An annotated data collection system to support intelligent analysis of intensive care unit data', in *Lecture Notes in Computer Science (including subseries Lecture Notes in Artificial Intelligence and Lecture Notes in Bioinformatics)*.
- Ulbricht, C., Dorffner, G. and Lee, A. (1998) 'Neural networks for recognizing patterns in cardiocograms', *Artificial Intelligence in Medicine*, 12(3), pp. 271–284.
- USFDA (2020) *USFDA MAUDE*.
- USFDA (no date) *USFDA*.
- Utekar, R. G. and Umale, J. S. (2018) 'Automated IoT Based Healthcare System for Monitoring of Remotely Located Patients', in *Proceedings - 2018 4th International Conference on Computing, Communication Control and Automation, ICCUBEA 2018*.

- Walsh, B. K. and Waugh, J. B. (2020) 'Alarm strategies and surveillance for mechanical ventilation', *Respiratory Care*, 65(6), pp. 820–831.
- Wee, A. N. and Sanderson, P. M. (2006) 'Do mnemonics help nurses learn melodic medical equipment alarms?', *Proceedings of the Human Factors and Ergonomics Society*, (May 2014), pp. 1039–1043.
- Wee, A. N. and Sanderson, P. M. (2008) 'Are melodic medical equipment alarms easily learned?', *Anesthesia and Analgesia*, 106(2), pp. 501–508.
- Wickens, C. D. and Carswell, C. M. (1995) 'The proximity compatibility principle: Its psychological foundation and relevance to display design', *Human Factors*, pp. 473–494.
- Wickens, C. D., Hollands, J. G., Banbury, S. and Parasuraman, R. (1999) *Engineering Psychology and Human Performance*. Prentice Hall New Jersey.
- Williams, S. and Beatty, P. C. W. (2005) 'Measuring the performance of audible alarms for anaesthesia.', *Physiological measurement*. England, 26(4), pp. 571–581.
- Winfrey, J. A. (2017) *Reducing Alarm Fatigue in Critical Care: Minimizing Alarm Occurrences*.
- Xiao, Y. and Seagull, F. J. (1999) 'An Analysis of Problems with Auditory Alarms: Defining the Roles of Alarms in Process Monitoring Tasks', *Proceedings of the Human Factors and Ergonomics Society Annual Meeting*, 43(3), pp. 256–260.
- Zong, W., Moody, G. B. and Mark, R. G. (2004) 'Reduction of false arterial blood pressure alarms using signal quality assessment and relationships between the electrocardiogram and arterial blood pressure', *Medical and Biological Engineering and Computing*, 42(5), pp. 698–706.

LIST OF PUBLICATIONS

- (a) Testing of Auditory Clinical Alarms in ICU/CCU

Journal: International Journal on Robotics, Automation and Sciences

Link: <https://journals.mmupress.com/index.php/ijoras/article/view/57>

- (b) Title: Human Factor Engineering Based Alarm System to Improve User Response in ICU/CCU

Journal: Journal of Critical Reviews

Link: <http://www.jcreview.com/index.php?mno=40682>

- (c) Software Based Clinical Alarm Simulator and HF based Alarm in ICU/CCU
International teleconference on technology and policy for supporting implementation of covid-19 response and recovery plan in Southeast Asia (ITTP-COVID19)

- (d) Fuzzy based multimodality clinical alarm in ICU/CCU.

ICHE2022-International Conference on Healthcare Engineering