FUZZY LOGIC BASED MULTIMODALITY CLINICAL ALARM SYSTEM FOR INTENSIVE CARE UNIT

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DEDICATION

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

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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 logik ialah teknik Kecerdasan Buatan (AI) yang paling kerap digunakan untuk memantau keadaan fisiologi pesakit yang memerlukan keputusan klinikal berdasarkan maklumat tanda vital.Fuzzy logik 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 logik 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 logik, Kadar Jantung (HR), Pernafasan (RESP), Tekanan darah noninvasif (NIBP) dan Tepu Oksigen (SPO2). Teknik fuzzy logik 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 logik dalam sistem penggera dengan ketara mengurangkan penggera palsu,memperbaiki respon pengguna, mengurangkan bahaya penggera dan meningkatkan keselamatan pesakit di ICU.

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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

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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, Isselbacherand 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.

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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

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(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.

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