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Article

Developing Reliable Digital Healthcare Service Using Semi-Quantitative Functional Resonance Analysis

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Abstract: Since entering the era of Industry 4.0, the concept of Healthcare 4.0 has also been put forward and explored by researchers. How to use Information Technology (IT) to better serve people's healthcare is one of the most featured emerging directions in the academic circle. An important field of Healthcare 4.0 research is the reliability engineering of healthcare service. Because healthcare systems often affect the health and even life of their users, developers must be very cautious in the design, development, and operation of these healthcare systems and services. The problems to be solved include the reliability of business process, system functions, and personal healthcare data. The Functional Resonance Analysis Method (FRAM) has been applied in reliability engineering for safety-critical systems in available studies, using both qualitative and quantitative approaches. However, the method has not been applied in the field of digital healthcare services development. Therefore, to narrow the gap, we present in this paper a semi-quantitative functional resonance analysis method to develop reliable healthcare services for diabetics. Moreover, this paper has tried to improve the reliability design of the service-oriented architecture (SOA) of traditional insulin pump therapy by system thinking.

Keywords: Reliability; safety-critical system; functional resonance analysis method; systemigram

1 Introduction

An insulin pump is a computerized medical device that simulates the working principle of human pancreas. It is used to regulate normal blood glucose level for patients with diabetes. Diabetic patients do not need to inject insulin regularly after using insulin pump. This not only reduces the pain caused by subcutaneous injection, but also achieves the timeliness and accuracy of insulin delivery [1,2]. Nevertheless, there are some urgent problems to be solved, such as the possible failure of the control system leads to the untimely or inaccurate dosage of insulin.

Since the digital healthcare service system is a safety-critical system that affects the life and health of patients, system failure should be rigorously avoided. When the insulin injection is not timely or the amount of insulin injection is insufficient, it may cause damage to internal organs and eyes due to hyperglycemia; When insulin injection is too frequent or excessive, users may fall into a coma due to hypoglycemia and even lose their lives in serious cases. In fact, the failure of any complex system may be unavoidable. The difficulty of developing the health care service is that it involves different people, organizations, devices, and information systems which form a System-of-Systems (SoS). The interaction between them is complex and nonlinear, which increases the uncertainty of system operation. In addition, the failure of safety critical systems is often unbearable for patients and the institutions that provide them with medical services. Therefore, the problem of how to avoid system failure as much as possible and how to protect users' safety in case of system failure are worth discussing.

Many researchers have explored the reliability engineering methodologies for safety critical systems development. Representative methods include Fault Tree Analysis (FTA), Man, Machine, Material, Method, Environment (4M1E) analysis, fishbone diagram, Failure Mode and Effects Analysis (FMEA), System Theoretic Accident Model and Processes (STAMP)/System Theoretic Process Analysis (STPA), AcciMap analysis, Functional Resonance Analysis Method (FRAM), etc. Among these methods, there are methods based on event decomposition, such as FTA, AcciMap, and fishbone diagram; There are also methods based on process analysis, such as STAMP/STPA and FRAM. At present, FRAM has attracted great attention of researchers. This is because FRAM can not only analyze the system reliability based on system process, but also extract the fault modes with complex causes that are difficult to find by other methods by discussing the internal relationship between functions. When analyzing complex safety critical systems, it is necessary to quantify the uncertainty of the system due to the need of risk level. Therefore, in addition to ordinary FRAM, many methods of quantitative expansion of FRAM have been proposed. At present, there have been studies on the use of FRAM in disaster response, accident cause analysis, safety process design, medical service risk analysis, etc., but there has been no report on the use of FRAM in the dependability engineering of digital health care service involving multiple stakeholders and different complex information systems. Therefore, this paper attempts to apply semi-quantitative FRAM and Monte Carlo simulation to digital health care service engineering. The contribution of this paper can be summarized as follows.

- A semi-quantitative application of FRAM to digital healthcare service development.
- Healthcare management platform, emergency response system, Insulin pump system, patient, smart devices, etc. are analyzed for reliability engineering at medical service level.
- Hazards in the operation of the insulin pump system are identified.
- The original system architecture design of the healthcare service for diabetics is improved based on the results of reliability analysis.

The remainder of this paper is organized as follows. Section 2 reviews the related work on reliability engineering for safety-critical systems and management of healthcare service, and explains the motivation of this study. Section 3 presents the semi-quantitative FRAM for dependability analysis of the healthcare service for the patients with diabetes. Section 4 proposes the countermeasures for providing reliable healthcare service for diabetic patients based on system thinking. Section 5 discusses the novelty, effectiveness, and limitation of the presented method. Finally, Section 5 concludes this paper and clarify the future direction of our research in the paper.

2 Related Work

There are many published safety-critical system engineering theories and methods. Ping et al. [2] proposed an access control scheme by introducing feature fusion and voiceprint, to prevent eavesdropping and therapy manipulation attacks against USB/uploader and insulin pump systems. Gouyon et al. [3] presented the validation of critical industrial process architectures from the point of view of safety and operation. Mamdikar et al. [4] developed a reliability analysis framework, which maps the Unified Modeling Language (UML) state chart model into the state-space model to analyze dynamic behavior and state transition probabilities of safety-critical systems. Grabbe et al. [5] advocated the use of FRAM as a risk assessment method in the development process of highly-automated vehicles, primarily to derive system design recommendations and secondly to provide essential insights into reducing the validation work. Pardo-Ferreira et al. [6] applied FRAM to increase understanding of construction activities for building concrete structures, in order to improve resilient safety management. Menezes et al. [7] compared the results of the application of FRAM and Performance Shaping Factors (PSF), to identify the critical functions in a chemical industry that affect process safety. Salehi et al. [8] modeled and analyzed hospital to home transition processes of frail older adults, in order to identify the challenges within the process. Zinetullina et al. [9] integrated FRAM and dynamic Bayesian Network for quantitative resilience assessment of chemical process systems. Kaya et al. [10] applied FRAM by integrating Monte Carlo simulations and a criticality matrix to explore how the system-based perspective would enrich the quantified risk-orientated analysis in a tram operating system. Patriarca et al. [11] reviewed over 1700 documents to uncover a number of characteristics of the FRAM research, both in terms of the method's application and of the authors contributing to its development. Patriarca et al. [12] evolved the traditional FRAM, proposing a semi-quantitative framework based on Monte Carlo simulation, to assess performance variability in complex systems such as ATM system. Liu et al. [13] developed FRAM into a dynamic research and analysis model, to enable FRAM analysis of important time points. Patriarca et al. [14] presented an evolution of traditional FRAM following a semi-quantitative approach based on Monte Carlo simulation for quantitatively modeling the interactions of system components. Rabena et al. [15] modeled a frequent activity in healthcare: Early detection of sepsis using FRAM, and analyzed 40 activities performed by nurses, doctors, secretaries, health workers and laboratory technicians; and illustrated possible and actual variability in the process. Bellini et al. [16] presented a fast-forward, cost-effective, and thorough enough framework to quantify resilience of complex socio-technical systems. Okano et al. [17] proposed an approach for deriving hazard transition sequences as a STAMP/STPA support method. Guzman et al. [18] compared an extension of the System-Theoretic Process Analysis (STPA-Extension) and the Uncontrolled Flows of Information and Energy (UFoI-E) method through a case study. Kim et al. [19] proposed and examined a quantitative scheme to use FRAM for risk assessment by defining rules for variability propagation and aggregation. Kumar et al. [20] developed a framework using a state-space model to quantify reliability in the design phase of the development life cycle to minimize the losses due to the system's failure after installation. Zhang et al. [21] presented a vehicle re-identification model based on optimized DenseNet121 with joint loss, to solve the computational complexity problem caused by local attribute marking.

The management of medical services has also attracted the interest of researchers. Valla [22] reviewed the diabetes management focusing on the latest insulin analogues, alternative insulin delivery systems, and the artificial pancreas. Lucidi et al. [23] proposed a simulation-based multi-objective optimization approach for health care service management. Ross et al. [24] applied FRAM to produce a sociotechnical systems model and identify opportunities to support fluoride varnish application for children attending general dental practice. Li et al. [25] presented a secure and efficient data management system named as EdgeCare for mobile healthcare systems. Kaya et al. [26] performed the FRAM on the drug administration process in a neonatal intensive care unit (NICU) to understand performance variability as conditions change, as well as to understand how variability in functions influences the system in terms of both success and failure. Kaya et al. [27] applied a semi-quantitative approach to the FRAM, facilitating a clear understanding of the critical interactions in the FRAM model for health-care process management. Al-Jaroodi et al. [28] defined the main objectives of Health 4.0 that integrates innovative technologies such as the Internet of Health Things (IoHT), medical Cyber-Physical Systems (medical CPS), health cloud, health fog, big data analytics, machine learning, blockchain and smart algorithms, and discuss advanced potential Health 4.0 applications. Zhang et al. [29] proposed a lightweight CNN classification model based on transfer learning to analyze chest Computed Tomography (CT) for timely COVID-19 diagnosis.

The literature survey shows that the methods of safety engineering and reliability analysis of safety critical systems and health care process have been studied by both qualitative and quantitative approaches. However, the overall exploration of reliable digital healthcare service development involving business process, information systems, and medical data could still remain a challenge. This may be complex and difficult to solve, as it not only involves the safety analysis of business process, but also needs to design the reliability of information systems. Therefore, we attempt to integrate FRAM with other software engineering methods in this paper, to propose an innovative scheme to design health care service from a perspective of reliable SoS development.

3 Semi-quantitative Approach to the FRAM towards Reliable Digital Healthcare Service

The insulin pump system is introduced, and the application of semi-quantitative approach to FRAM toward reliability engineering for the system is presented in Sections 3.1 and 3.2, respectively.

3.1 The Insulin Pump System

Fig. 1 illustrates the hardware components and architecture of an insulin pump system [2,22]. The blood glucose sensor measures the blood glucose level of a diabetic by measuring the conductivity of blood. The embedded control system (controller) of the insulin pump calculates the necessary insulin dosage based on the measured blood glucose value or the personalized needs of patients. The pump delivers a unit of insulin according to a pulse sent by the controller. For example, 5 units of insulin are needed, the controller sends 5 pulses to the pump. Obviously, the insulin pump is a safety critical system, because if it does not work or does not work properly, the user’s health would be damaged, or they may fall into a coma due to abnormal blood glucose levels. The process for users to use the insulin pump system is summarized as shown in Tab. 1.

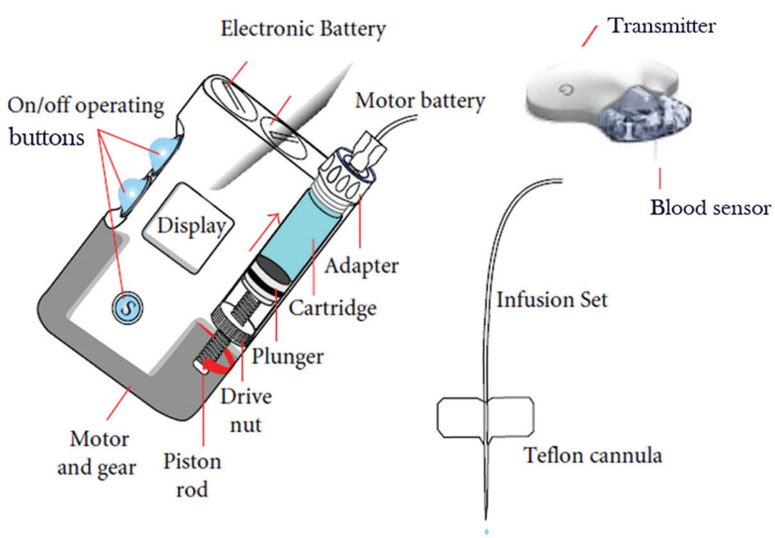


Figure 1: Hardware structure of an insulin pump [2,22]

Table 1: Function list of the insulin pump system

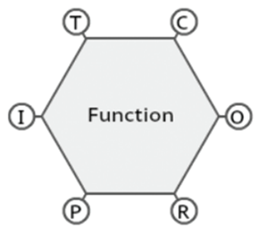
No.	Function	Description
01	Diagnose	Diabetic patients receive the diagnosis of their medical care team to determine whether they need to control the condition by injecting insulin
02	Train	Diabetic patients who need and are willing to accept insulin pump therapy should attend lectures on the use of insulin pump, and learn about the installation, use, cleaning, emergency handling of the system
03	Evaluate	The medical team and patients themselves assess whether insulin pump therapy program could be used
04	Attach the infusion set	Users attach the infusion set (tubing connected to a Teflon cannula) to the reservoir outlet, and insert the infusion set to their bodies
05	Blood glucose measurement	The blood sensor measures the blood glucose level of a diabetic by measuring the conductivity of blood
06	Calculate insulin dosage	The controller calculates the necessary insulin dosage based on the measured blood glucose value. Additionally, insulin dosage can also be programmed by the users
07	Insulin injection	The pump releases insulin in two ways: a steady flow throughout the day and night, and an extra dose at mealtime in order to metabolize rising blood sugar from the food
08	Monitoring	Users can confirm their blood glucose value and remaining insulin level through the LCD screen on the insulin pump
09	Data collection	The insulin pump records and stores user’s insulin injection volume and the blood glucose value after insulin injection within three months, in order to provide patient’s condition materials for the next diagnosis
10	Alert	When the battery is low, blood glucose value is abnormal (too high or too low), or remaining insulin is insufficient, the LCD screen will display a corresponding warning
11	Replenish insulin	When the pump begins running out of insulin, new insulin will need to be loaded into the pump
12	Replace insulin	Users should regularly change the insulin in the pump according to the manufacturer’s recommendations
13	Ambulance dispatch request (If necessary)	When the patient’s blood glucose is abnormal or physical condition deteriorates sharply, a call should be made for an ambulance
14	Transportation of patient (If necessary)	The ambulance takes the patient to the emergency center

3.2 Research Method

3.2.1 The Functional Resonance Analysis Method (FRAM)

Traditional system reliability analysis methods such as FTA, can be used to explicitly analyze the cause of system failures with fault tree structure; STAMP/STPA can identify the factors that make interaction between components undesirable. These methods mainly focus on the failure mode of systems. Instead reliability analysis methods using FRAM not only discuss about failure patterns, but also consider how multiple functions interact with each other in the day-to-day operation of the system, and analyze the uncertainty of systems related to safety assurance.

As shown in Fig. 2, a FRAM model represents the functions of a system using a hexagon with six aspects, i.e., I (input of the function), T (time constrains that may affect the operation of a function), control (control strategy for operating the function), O (output of the function), resource (requirements that are needed for operating the function), and P (preconditions for operating the function). System analysts try to find the possibility of hazard that is not easy to find in the normal state by analyzing the coupling of interactions between different system functions when the target system is operated. The possibility of hazard is also called uncertainty.



I	Input
T	Time
C	Control
O	Output
R	Resource
P	Precondition

Figure 2: An example of functions in a FRAM model

3.2.2 A Semi-quantitative Application to the FRAM towards Reliable Digital Healthcare Service

The original FRAM is a qualitative analysis method that can be used to consider the variability of each function output in terms of time and accuracy, as well as the impact on downstream functions. The coupling between related functions is then investigated to analyze the uncertainty of the system. The uncertainty may be positive or negative, which needs to be analyzed and discussed according to facts of each situation. However, this qualitative analysis method is inadequate when dealing with the reliability of large-scale complex systems, because it is necessary to evaluate the coupling degree between functions for identifying key functions and critical path. The semi-quantitative analysis approach to simulate and deduce the resonance of system function by Monte Carlo method based on simulation is therefore applied to FRAM. Before simulation, it is necessary to define the probability of the output of different types of functions. As presented in Fig. 3, we adjusted the probability parameters for simulation of existing studies [10,14], to meet the needs of our study in this paper. For example, if a function is a technological one, i.e., executed by a machine, computer program, or AI, the output of the function is 90% on time, 4% too early, 4% too late, and 2% omitted.

The variability regarding time and precision of output of the functions is evaluated using a numerical 1–4 scale [14] as shown in Tab. 2.

Amplitude modulation coefficient of Function k to Function k' is defined as shown in Eq. (1). If n function has amplifying effect on its downstream function, the amplitude modulation influence coefficient is 2; If the function has no effect on its downstream function, the amplitude modulation influence coefficient is 1; If the function has damping effect on its downstream function, the amplitude modulation influence coefficient is 0.5.

$$A_k^{k'} = \begin{cases} 2.0, & \text{amplifying effect} \\ 1.0, & \text{no effect} \\ 0.5, & \text{damping effect} \end{cases} \tag{1}$$

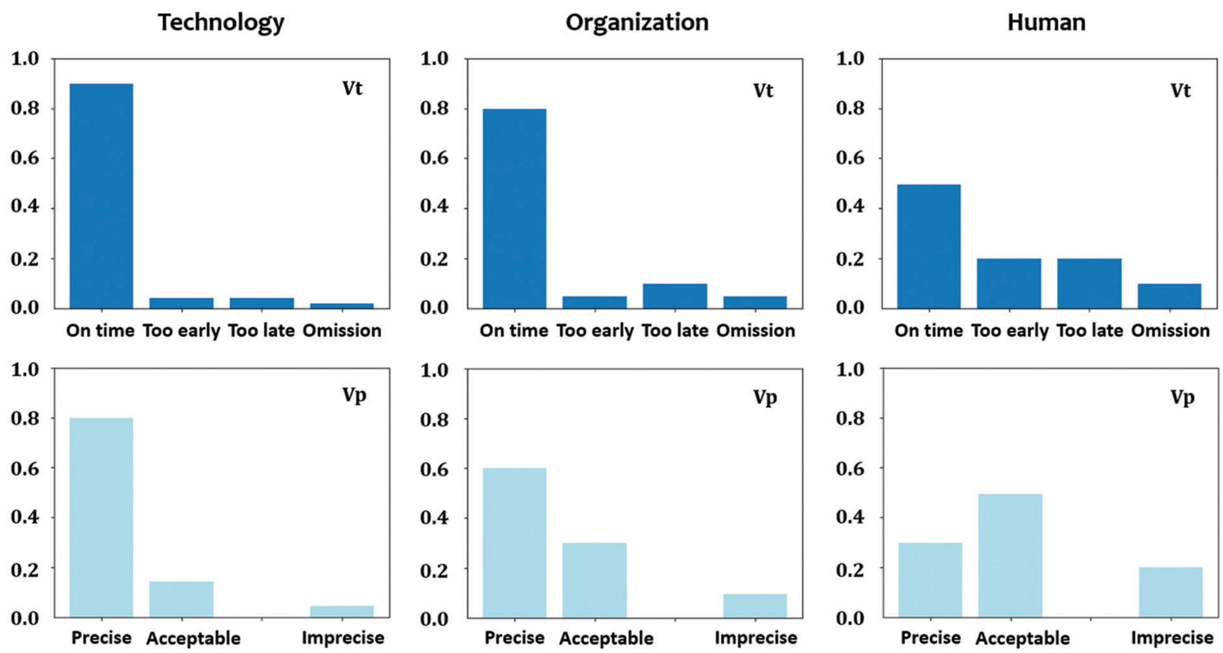


Figure 3: Probability distribution for the variability of the output from several different types of functions

Table 2: The 1–4 scale for variability assessment

Aspect of output	Variability	Numerical value
Time (Vt)	On time	1
	Too early	2
	Too late	3
	Omission	4
Precision (Vp)	Precise	1
	Acceptable	2
	Imprecise	4

Thus, the variability of a function can be expressed by Eq. (2), where n is the number of upstream functions. V_t denotes the variability of time of the upstream function. V_p denotes the variability of time and precision of the upstream function. $A_{t_k}^{k'}$ and $A_{p_k}^{k'}$ are the amplitude modulation coefficient of time and precision of the upstream function, respectively. Furthermore, if a function has multiple upstream functions, the variability generated by these upstream functions is combined by multiplication.

$$V = \prod_{i=1}^{n} (V_t * A_{t_k}^{k'} * V_p * A_{t_k}^{k'})i \quad (2)$$

The FRAM model of the insulin pump system is shown in Fig. 4. The functions of the system are connected in the order of system flow. The types of the functions, and variability of time and precision of the output are also analyzed and specified in the model (the functions with wavy line). We simulate by using the Monte Carlo method. Specifically, we generate a random number between 0–1. While identifying the type of function, we judge which interval of the random number is located in the probability distribution shown in Fig. 3 to determine the value of variability. For instance, for a technological function, if the generated random number for simulation of time of output is 0.6, since the value is in range [0.00, 0.85], the simulation result of the variability of the system function output in terms of time is therefore 1: On time (see Fig. 3 and Tab. 2). A part of the Monte Carlo simulation results are presented in Fig. 5, where the bar graph indicates the number of occurrences of variability value, and the line graph shows the cumulative probability distribution.

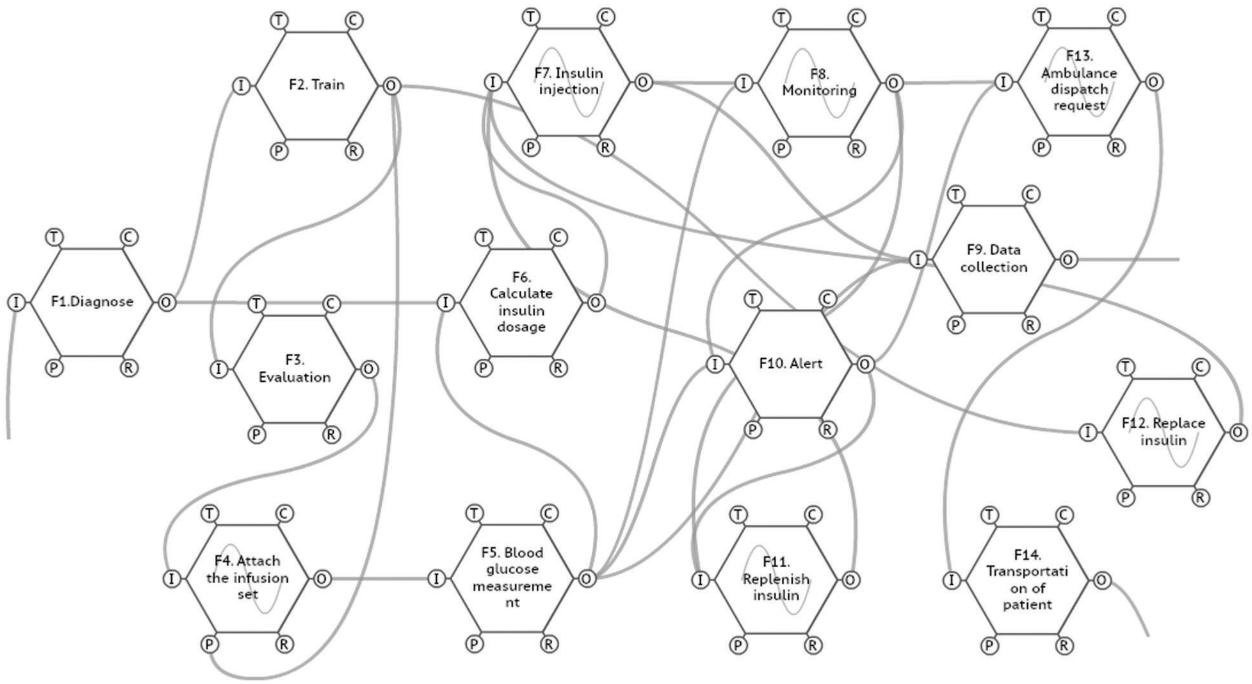


Figure 4: FRAM model for reliability analysis of the insulin pump system

Tab. 3 shows the parameters and results of Monte Carlo simulation used for uncertainty evaluation. We simulate 1000 times, and the threshold for key functions identification is set to 16 (the maximum variability in time multiplied by the maximum variability in precision of output of functions) [30]. If more than 95% of the simulation results do not exceed this threshold, the function is relatively reliable; Otherwise, the function has high uncertainty and should be listed as a key function that needs reliability engineering. The extracted key functions are F5, F7, F10, F11, and F14. Fig. 6 shows the critical paths of the insulin pump system. The red curve indicates that variability outside the tolerance range of the system is likely to occur during the transition of system functions. For example, F11 is a key function and the output of its upstream function F8 has potential variability in terms of time and precision, the transition F8 → F11 is therefore a critical path. Tab. 4 summarizes the potential variability of functional resonance of the critical paths.

4 System Engineering towards Reliable Digital Healthcare Service for Diabetic Patients

Among the potential risks listed in Tab. 4, F4 → F5 may lead to user's health damage. The poor setting of insulin pump affects the absorption of insulin and causes hyperglycemia; Or the insulin pump may be attached in the same part of body for a long time, resulting in the decomposition of body tissue in that part and affecting insulin absorption. In this regard, we suggest implementing the insulin pump system with an installation detection function to evaluate the installation effect by measuring the blood flow resistance at the initial stage of installation. If the installation is poor, the system should immediately give feedback to its user. In addition, F8 → F11 may cause insufficient insulin supply, as user may not supplement insulin and battery power in time due to negligence; F12 to F7, insulin can lose its potency if the user does not replace insulin potion on time. To resolve this problem, our suggestion is to connect the insulin pump through near field communication (NFC), such as Bluetooth and the healthcare app on the smartphone, to monitor the remaining insulin and battery power of the insulin pump in real time, and send vibration prompt and voice warning if the remaining amount is too low.

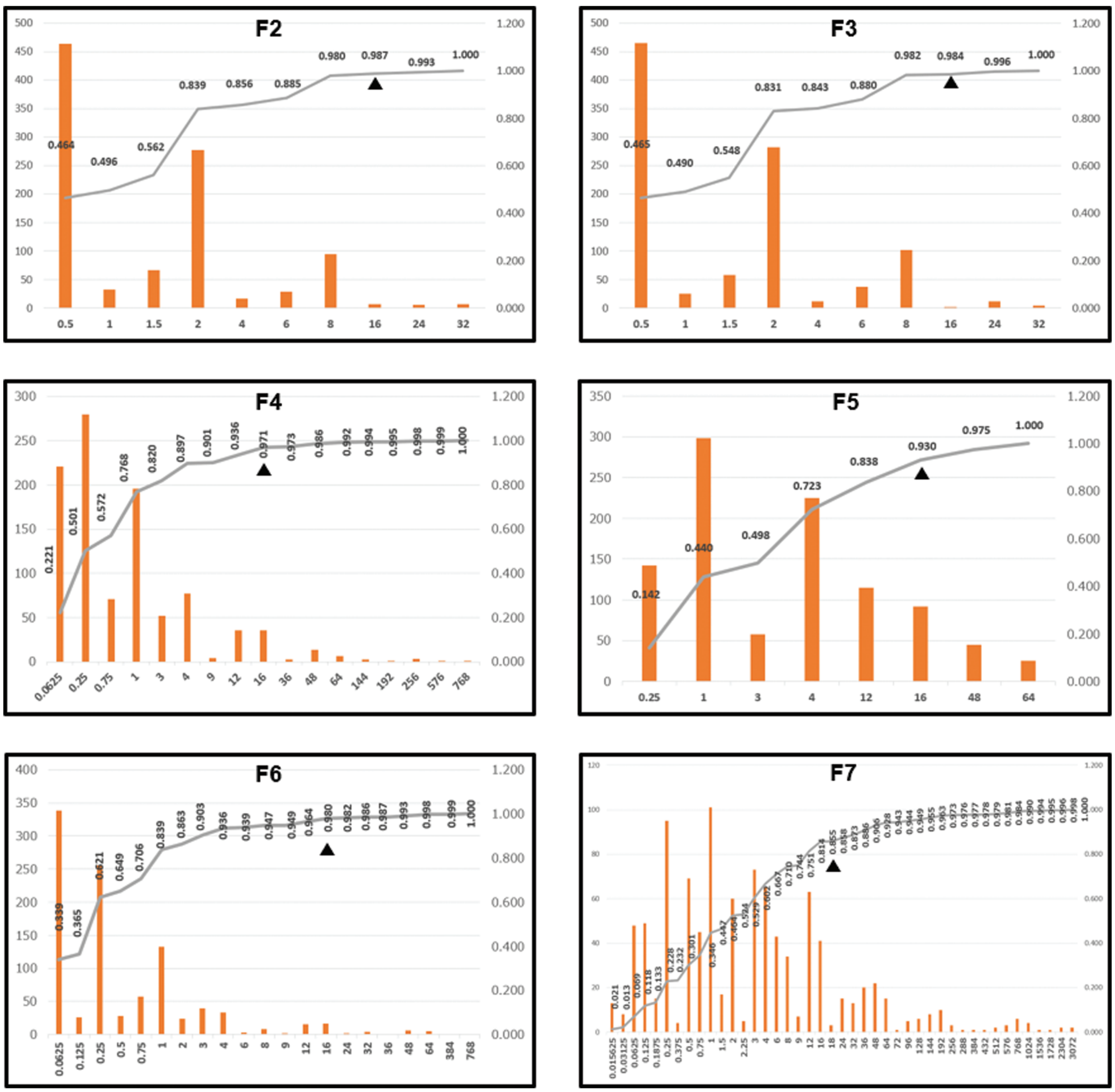


Figure 5: Simulation results of variability for the functions of the insulin pump system (excerpt)

Table 3: Parameter and results of Monte Carlo simulation of functional coupling

Functions		$A_{t_k}^{k'}$				$A_{p_k}^{k'}$			Variability		
k	k′	1	2	3	4	1	2	4	Thd_{cpl}	$P > Thd_{cpl}$	Coupling
F04	F05	0.5	1.0	2.0	2.0	0.5	1.0	2.0	16	0.930	Yes
F06	F07	0.5	0.5	2.0	2.0	0.5	1.0	2.0	16	0.855	Yes
F11	F07	0.5	0.5	2.0	2.0	0.5	1.0	2.0	16	0.855	Yes
F12	F07	0.5	0.5	2.0	2.0	0.5	1.0	2.0	16	0.855	Yes
F05	F10	0.5	2.0	2.0	2.0	0.5	1.0	2.0	16	0.933	Yes
F08	F10	0.5	2.0	2.0	2.0	0.5	1.0	2.0	16	0.933	Yes
F08	F11	0.5	2.0	2.0	2.0	0.5	1.0	2.0	16	0.941	Yes
F10	F11	0.5	1.0	2.0	2.0	0.5	1.0	2.0	16	0.941	Yes
F13	F14	0.5	2.0	2.0	2.0	0.5	1.0	2.0	16	0.895	Yes
F01	F02	1.0	1.0	1.0	1.0	0.5	1.0	2.0	16	0.987	No
F02	F03	1.0	1.0	1.0	1.0	0.5	1.0	2.0	16	0.982	No
F02	F04	0.5	1.0	2.0	2.0	0.5	1.0	2.0	16	0.971	No
F03	F04	0.5	1.0	2.0	2.0	0.5	1.0	2.0	16	0.971	No
F01	F06	0.5	0.5	2.0	2.0	0.5	1.0	2.0	16	0.980	No
F05	F06	0.5	2.0	2.0	2.0	0.5	1.0	2.0	16	0.980	No
F05	F08	0.5	2.0	2.0	2.0	0.5	1.0	2.0	16	0.996	No
F07	F08	0.5	2.0	2.0	2.0	0.5	1.0	2.0	16	0.996	No
F05	F09	0.5	1.0	1.0	2.0	0.5	1.0	2.0	16	0.997	No
F07	F09	0.5	1.0	1.0	2.0	0.5	1.0	2.0	16	0.997	No
F02	F12	1.0	1.0	1.0	1.0	0.5	1.0	2.0	16	0.982	No
F08	F13	0.5	1.0	2.0	2.0	0.5	1.0	2.0	16	0.960	No
F10	F13	0.5	1.0	2.0	2.0	0.5	1.0	2.0	16	0.960	No

When F8 → F10, fatal accidents may happen. Users' negligence or abnormal vision and hearing lead to failure to notice the alarm of too high or too low blood sugar level. As for F13 → F14, users may fall into a coma due to hypoglycemia and cannot call an ambulance. In this regard, our suggestion is to align the user's smart bracelet with the healthcare app through NFC and report the user's location and heart rate information in real time as an aid to the user's hypoglycemia detection. Moreover, it is necessary to link the user's healthcare app with the hospital's health management platform and the emergency response system of the emergency center, so that when the user's blood glucose is abnormal (especially severe hypoglycemia), an ambulance can be dispatched to carry the patient for rescue. System thinking [31] is a methodology of software engineering and system engineering considering the connection and the relation of systems in System of Systems (SoS). The starting point for systems thinking is to view the problem as a systemic structure. Fig. 7 shows a systemigram model [32] reflecting the modified service-oriented architecture (SOA) of the insulin pump therapy for diabetic patients. The dotted line shear and numbers respectively represent the modified or newly added functions, and the critical paths protected by them.

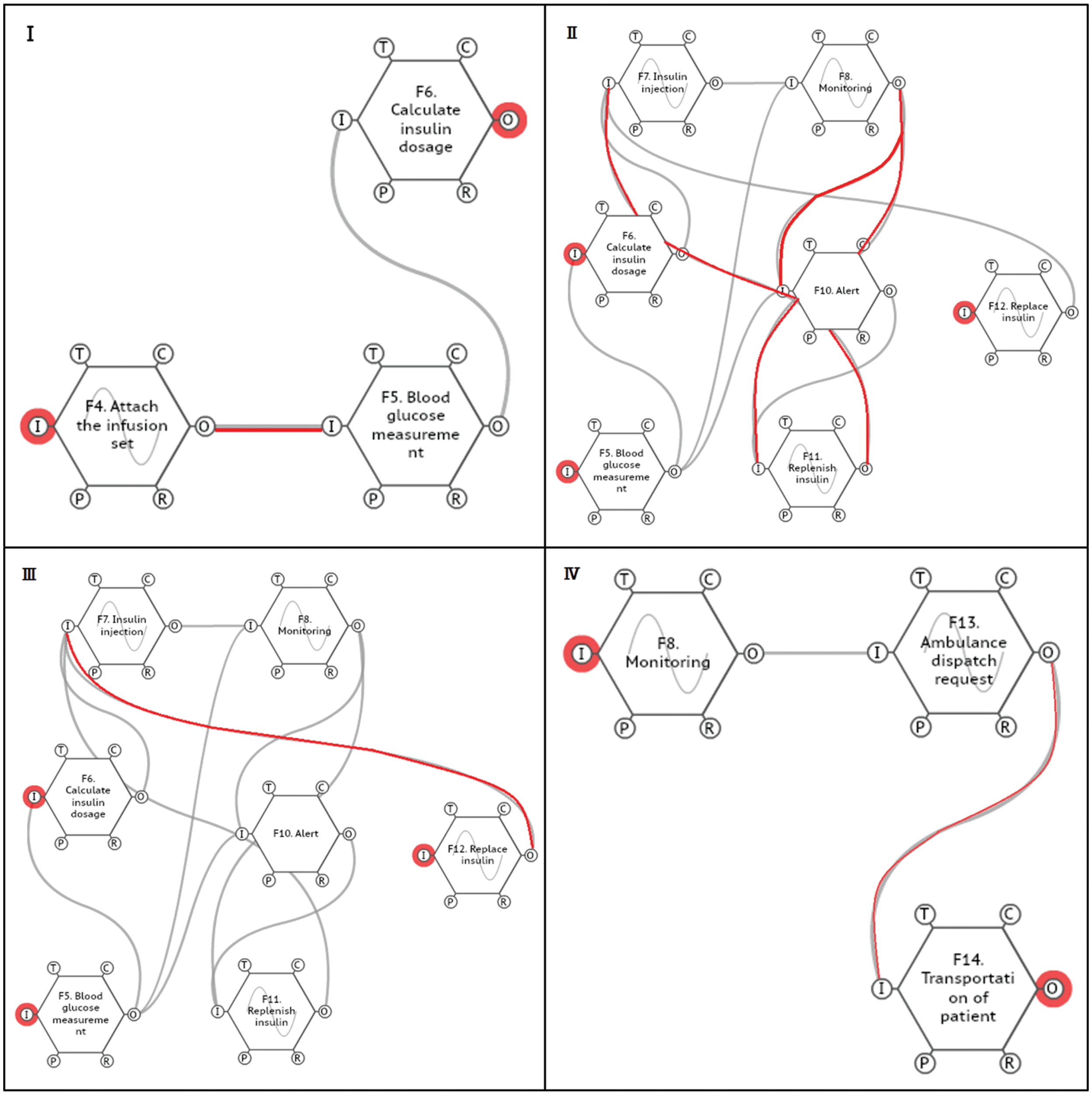


Figure 6: Critical path of the insulin pump system

5 Discussion

This section discusses the novelty, effectiveness and threat to validity of our study in this paper.

5.1 Novelty

The reliability and safety analysis method based on FRAM has been widely used in the design of safety-critical systems. In addition, after Patriarca et al. creatively proposed the semi-quantitative analysis method using Monte Carlo method [12], the ability of FRAM for large-scale complex systems reliability assessment has been improved by using the simulation approach for evaluating the uncertainty generated by system functional resonance. However, at present, there is less research on the application of FRAM in digital medical service development. Moreover, Although Kaya et al. presented a medical service safety management method based on FRAM [27], it is based on the analysis of process, rather than how to apply IT to healthcare service development. The purposes are therefore different. Tab. 5 compares the characteristics of this paper and several existing studies.

Table 4: Potential variability of the extracted key functions in time or precision

Critical path	Transition between functions		Variability	
	Upstream	Downstream	Time	Precision
No.1	F4: Attach the infusion set	F5: Blood glucose measurement	N/A	Poor installation; Body tissue damage caused by improper setting
No.2	F8: Monitoring	F10: Alert	Not aware of the alarm	N/A
	F8: Monitoring	F11: Replenish insulin	The remaining insulin quantity and battery power are not confirmed in time or omitted	Misreading
	F11: Replenish insulin	F7: Insulin injection	Delayed or missed insulin replenishment	N/A
No.3	F12: Replace insulin	F7: Insulin injection	Infrequent or missing insulin replacement	Poor installation
No.4	F13: Ambulance dispatch request	F14: Transportation of patient	N/A	The patient falls into a coma due to hypoglycemia and is unable to call an ambulance

5.2 Effectiveness

This paper presents an application of reliability engineering of healthcare service for diabetic patients based on the semi-quantitative FRAM, and shows the availability of this method through a case study of an insulin pump system. First, we clarify the function list of the system by analyzing the system process, and analyze the amplitude modulation coefficient of the output of downstream functions. We then adjust the parameters of existing studies using FRAM based on Monte Carlo method, in order to evaluate the variability of system functions through simulation. As a result, 5 key functions and 4 critical paths of the system are identified.

We analyze the potential accident scenarios on the critical path from the aspects of time and precision, and carry out the reliability development based on system thinking in the Section 4. The results show that the method shown in this paper can be applied to system engineering of reliable digital medical service to meet the needs for Healthcare 4.0. According to the simulation results, key functions of the insulin pump system were extracted, and system thinking was utilized to reliability engineering of the system. This proves that the semi-quantitative FRAM can be applied to the design and development of health care service. In addition, the combination of FRAM and systemigram model proves that modeling for reliability engineering and system engineering can be conducted concurrently in system design stage, which is often ignored in the current software engineering practice.

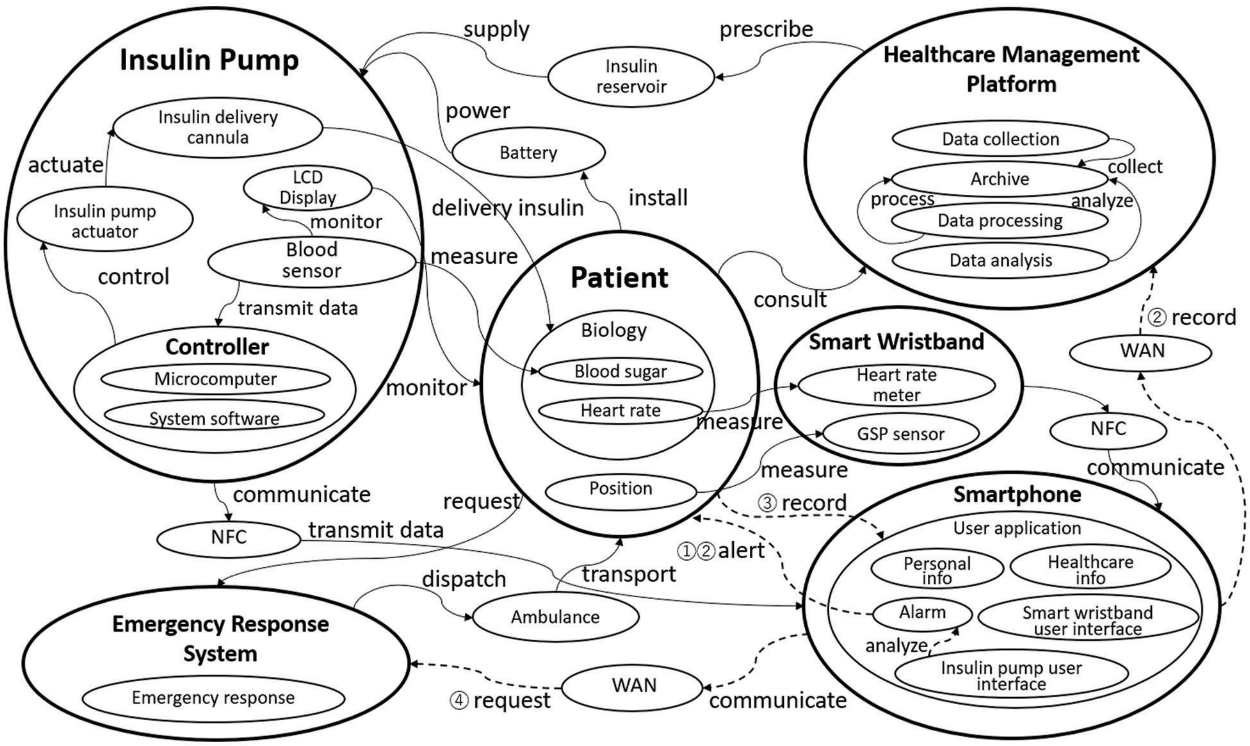


Figure 7: Systemigram of the revised scheme of reliable digital healthcare service for diabetics

Table 5: Comparison of this research and some existing studies on safety-critical systems engineering

Study	Domain	Approach	Research method	Evaluation
Gouyon et al. (2020) [3]	Industrial process management	Automaton	Qualitative	Case study
Grabbe et al. (2020) [5]	Autonomous driving	FRAM, Monte Carlo simulation	Semi-quantitative	Simulation, case study
Salehi et al. (2021) [8]	Hospital-to-home transition processes of patients	FRAM	Qualitative	Interview, case study
Patriarca et al. (2017) [14]	Environmental risk auditing	FRAM, Monte Carlo simulation	Semi-quantitative	Simulation, Case study
Raben et al. (2018) [15]	Early detection of sepsis	FRAM	Qualitative	Case study

(Continued)

Table 5 (continued)

Study	Domain	Approach	Research method	Evaluation
Okano et al. (2020) [17]	Railroad crossing safety	STAMP/STPA	Qualitative	Case study
Kumar et al. (2022) [20]	Reliability analysis for nuclear Power plant control system	Petri net, Markov model, model checking	Quantitative	Case study
Huang et al. (2022) [33]	Railway dangerous goods transportation	FRAM, N-K Model	Quantitative	Case study
Oleo et al. (2022) [34]	Food safety incident analysis	AcciMap model	Qualitative	Case study
Our research	Reliable digital healthcare service	FRAM, Monte Carlo simulation	Semi-quantitative	Simulation, Case study

5.3 Threat to Validity

System reliability analysis using FRAM requires a high level of understanding of the target systems or service. Otherwise, biased conclusions may be drawn when analyzing the interaction between functions. Different people have different starting points and are likely to provide different useful views. In addition to time and precision, other factors, such as environment, may also affect the operation results of functions. In the process of analysis, it is better to convince different stakeholders such as doctors, patients, developers and analyst for contract analysis. This paper only discusses the digital medical service around the insulin pump system, without evaluating the adaptability of patients with other diseases, e.g., heart disease, severe obesity, physical disability, etc. Furthermore, new problems may be generated by reliability development, such as the security of patient personal information and medical data, and personal privacy concerns.

6 Conclusion

In the IoT era, while digital healthcare services can bring more convenient health care to patients, there are also potential risks to be resolved. How to ensure the life and health of users in complex digital healthcare processes is one of the urgent problems to be addressed. Researchers and engineers have demonstrated the superiority of FRAM in the field of safety analysis and reliability engineering. However, so far, there is no exploration on the application of FRAM in digital healthcare services development. To fill this gap, this paper presented a semi-quantitative application of FRAM to digital healthcare service development. Hazards in the operation of insulin pump system are identified and analyzed, and the original system architecture design of the healthcare service for diabetics is improved based on the results of reliability analysis. Although this paper only discusses the digital medical service utilizing the insulin pump system, it can be expected to be applied to other healthcare service for patients with other health problems such as heart disease. Furthermore, we found that FRAM can be combined with system thinking approach [31,32] to implement reliability engineering for SoS (see Section 4).

As the future work, we plan to study how to realize optimization when a variety of reliability countermeasures coexist. In addition, going to the hospital to interview the patients and their healthcare team to verify the effectiveness of this study is also the future direction of our research in this paper.

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