RESEARCH ARTICLE

Non-invasive Continuous Glucose Monitoring (CGM) System Reliability Analysis Based on the DFMEA Model

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Abstract

Non-invasive continuous glucose monitoring (CGM) systems offer the advantage of non-invasive, real-time dynamic glucose monitoring, marking a significant advancement in diabetes management. However, the complexity of their sensing principles and operational mechanisms make systems vulnerable to various factors, which may introduce measurement bias or cause system interruptions and thereby compromise patient safety and monitoring effectiveness. To address these challenges, the Design Failure Mode and Effects Analysis (DFMEA) method is employed to identify and prioritize risks by assigning expert-based scores to critical components, ultimately enabling targeted improvements for high-risk failure modes to ensure system safety. This paper decomposes the key functional modules of the non-invasive CGM systems, identifies the potential failure modes within each module, and utilizes expert evaluation of severity, occurrence frequency, and detectability to determine Risk Priority Numbers (RPNs). Based on the RPNs, corresponding improvement strategies are proposed for high-risk failure modes, with the aim of mitigating system risks and enhancing the overall reliability of the non-invasive CGM systems.

Keywords: non-invasive CGM system, DFMEA, RPNs, failure analysis, risk prioritization.

1 Introduction

According to the International Diabetes Federation (IDF) 2024 statistics, the global diabetes population has reached 643 million [1]. This number is projected to rise to 853 million by 2050, accounting for nearly one-eighth of the world's population. As a chronic disease, blood glucose monitoring plays a crucial role in enabling diabetes patients to self-manage their condition, adjust their lifestyle, and reduce the risk of elevated blood sugar levels and late-stage complications.

Blood glucose monitoring can be broadly categorized into self-monitoring of blood glucose (SMBG) and continuous glucose monitoring (CGM). SMBG relies on finger-prick blood sampling to measure glucose levels at discrete time points. This method not only causes pain during each measurement but also increases the risk of skin infections [2]. More importantly, SMBG provides only discrete measurements and therefore fails to capture crucial blood glucose fluctuations, such as postprandial

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peaks or nocturnal hypoglycemia. Consequently, it often misses blood glucose spikes and cannot adequately reflect the patient's full-day blood glucose dynamics. In contrast, non-invasive CGM systems continuously track glucose concentration changes in subcutaneous tissue fluid through non-invasive sensing technology. This approach avoids the pain and discomfort associated with SMBG devices while enabling accurate detection of key glucose fluctuation patterns. Consequently, non-invasive CGM offers more effective support for medical treatment to achieve efficient blood glucose management.

The CGM system is characterized by its compact size, complex structure, and the requirement for continuous glucose monitoring, placing higher demands on system safety and reliability. Existing studies on CGM systems primarily focus on frequency statistics and root cause analysis for certain scenarios, like detachment rates and fault detection during clinical application [3, 4]. However, those studies have not thoroughly explored the underlying causes of such failure modes from a system reliability design perspective. Conducting in-depth analysis of these failure modes during the design phase and implementing reliability-oriented design optimization can control risks at the source, thereby avoiding the need for extensive troubleshooting and correction actions during later stages of application.

DFMEA is a well-established systematic failure analysis method [5]. It involves decomposing a system into its constituent to identify potential failure modes and their subsequent impacts. Experts assign scores across three dimensions: Severity (S), which reflects seriousness of failure consequences), Occurrence (O), which indicates the likelihood of failure, and Detection (D), which measures the probability of detecting the failure before it occurs. These three scores are multiplied to obtain the Risk Priority Number (RPN), which serves as a quantitative indicator of the risk level associated with each failure mode. High RPN values highlight critical failure modes that require design improvement to reduce overall system risk.

Accordingly, this paper conducts a safety and risk assessment of the CGM system using the DFMEA model. The analysis begins with the decomposition of the system into five key modules, including the sensor front-end module, the signal measurement and processing module, the power consumption and management module, communication and application (APP) module, and the wearable device packaging module. Expert assessments of severity, occurrence and detectability of key failure modes are then quantified, and the RPN is calculated as the product of these three metrics. Based on the ranking of RPNs, high-risk failure modes are identified and corresponding design improvement strategies are proposed.

The structure of this paper is as follows: Section 2 presents the DFMEA methodology and evaluation criteria. Section 3 provides a structural analysis of the CGM system and performs the DFMEA-based failure analysis, followed by proposed improvement measures for high-risk patterns. Finally, the main research content of this paper is summarized in Section 4.

2 DFMEA Analysis

2.1 DFMEA Methodology

DFMEA is a systematic failure analysis method used to identify potential failure modes of system [6]. It evaluates the impact of each failure mode and determines corresponding improvement measures to mitigate risks. The implementation process of DFMEA primarily includes structural analysis, functional analysis, failure analysis, risk analysis, and optimization.

When conducting DFMEA analysis [7], the first step is to comprehensively identify all potential failure modes of the system under study, including any conditions that may cause malfunction or abnormal operation. For each identified failure mode, expert scores are assigned for severity, occurrence probability, and detectability. The RPN is then calculated based on the formula $\mathrm{RPN} = \mathrm{S} \times \mathrm{O} \times \mathrm{D}$. Failure modes are prioritized according to their RPN values. A higher RPN indicates a greater associated risk. Such modes require priority improvement measures, such as design optimization or process enhancements, to enhance system reliability and safety.

2.2 DFMEA Evaluation Criteria

The DFMEA evaluation framework requires the determination of three parameters for each failure mode: S, O, and D. These parameters are assigned by comparing the failure mode against predefined evaluation criteria. Since the evaluation criteria depend on the characteristics and application context of the system under analysis, the first step in conducting DFMEA analysis for critical components or an integrated systems is to define approximate

parameter evaluation standards.

In this study, the evaluation criteria for the three parameters are referenced from the established DFMEA application for a PET/MR system reported in [8]. Although non-invasive CGM systems and PET/MR systems differ in sensing principles and operations, they share essential characteristics as safety-critical medical devices, including high requirements for measurement accuracy, regulatory constraints, and direct implications for patient safety. To the best of the authors' knowledge, systematic DFMEA-based evaluation criteria specifically tailored for non-invasive CGM systems have not yet been reported in the existing literature. Therefore, the PET/MR-based criteria are referenced in the DFMEA evaluation of the non-invasive CGM devices. The evaluation criteria for the S, O, and D of failure modes are shown in the Tables 1, 2 and 3.

3 Case Study

3.1 Structure and Function of CGM Systems

Within the non-invasive CGM technology framework, the reverse iontophoresis method is one of the commonly employed approaches [9]. Its fundamental principle involves applying a low-intensity electrical current to the skin surface, thereby utilizing the electroosmosis effect to drive glucose molecules from the interstitial fluid in the skin's stratum corneum toward the skin surface. The sensor then captures the resulting glucose concentration signal and converts it into blood glucose data.

The overall architecture of a non-invasive CGM system can be decomposed into five functional modules. The sensing front-end module incorporates specific structural designs to facilitate the reverse iontophoresis process, thereby improving the efficiency of glucose extraction and providing the foundation for subsequent signal acquisition. The signal measurement and processing module constitutes the core of the system, responsible for accurately detecting glucose-related signals and performing computational analysis. Through electrochemical reactions, this module converts glucose concentration into measurable electrical signals and conducts preliminary signal processing. The power consumption and management module supplies and regulates energy to ensure stable and continuous system operation. The communication and application (APP) module enables data exchange between the system and external, allowing users to visualize blood glucose measurement, configure device parameters, and manage device functions. Finally, the wearable device packaging module integrates and encapsulates all components, providing structural protection while ensuring user comfort during daily wear. These modules work collaboratively support the functionality of the non-invasive CGM system and are associated with distinct failure risks. The detailed composition and interconnections of each module are illustrated in Figure 1.

3.2 DFMEA-based failure analysis

To conduct a comprehensive and systematic assessment of the potential failure risks in the non-invasive CGM system, this section applies the DFMEA methodology to analyze failure modes at the system and component levels. A five-member expert team was established, comprising two CGM device designers, two reliability engineers, and one R&D specialist. This multidisciplinary composition ensures that the evaluation incorporates perspectives from device design, reliability engineering, and practical implementation.

By examining the components and functions of each module, potential failure modes, causes, and consequences were identified. Following the DFMEA procedures introduced in Section 2, a total of 18 failure modes were quantified and evaluated. The S, O, and D ratings were determined through consensus based on the established evaluation criteria. The resulting RPNs were then calculated to rank the identified failures modes. Table 4 presents selected failure modes with relatively high RPNs, which are considered critical to system safety and performance.

As shown in Table 4, the voltage regulator exhibits the highest RPN (162), followed by Microcontroller unit (MCU) short-circuit failure (RPN=144) and the current source deviation (RPN =135). The voltage regulator is responsible for providing a stable reference voltage for the analog front-end and the analog-to-digital converter (ADC). The inaccurate output voltage may not immediately cause catastrophic failure but lead to reference drift in the ADC and analog front-end, thereby degrading performance accuracy, the severity was rated as S=6. The occurrence rating O=3 was selected based on the presence of basic preventive measures such as filter capacitors, which reduce the likelihood of voltage instability, however, susceptibility to external electromagnetic interference and power fluctuations remains, particularly in wearable and mobile usage

Table 1. Occurrence evaluation criteria of DFMEA [8].

Likelihood of Failure Occurrence	EVALUATION CRITERIA	O
Very High: Continuous Failure	$\geq$ 100 times per 1,000 samples	10
	70 times per 1,000 samples	9
High: Frequent Failure	50 times per 1,000 samples	8
	20 times per 1,000 samples	7
Medium	10 times per 1,000 samples	6
	5 times per 1,000 samples	5
	1 time per 1,000 samples	4
Low	0.5 times per 1,000 samples	3
	0.1 times per 1,000 samples	2
Very Low	$\leq$ 0.01 times per 1,000 samples	1

Table 2. Severity evaluation criteria of DFMEA [8].

Consequence	Evaluation Criteria	S
Severe Hazard Without Warning	Affects the personal safety of patients or medical staff without any failure warning, violates government regulations, or causes extremely significant economic losses	10
Severe Hazard With Warning	Occurs with failure warnings, affects the personal safety of patients or medical staff, violates government regulations, or causes major economic losses	9
Very High	Complete loss of basic functions of the system and modules, resulting in irrecoverable damage	8
High	Complete loss of basic functions of the system and modules, but functions can be restored	7
Medium	System or module can operate, but basic performance degrades (fails to meet performance index requirements)	6
Low	System or module can operate, but secondary functions are lost (equipment can perform detection, but designed functions such as comfort, convenience, and reliability are lost)	5
Very Low	System or module can operate, but secondary functions are weakened (equipment can perform detection, but designed functions such as comfort, convenience, and reliability are reduced)	4
Minor	System functions normally and meets performance requirements, with the system status displaying prompt information (parameters exceed warning thresholds)	3
Very Minor	Product functions normally and meets performance requirements, with the system or module recording internal prompt information	2
None	No identifiable consequences	1

scenarios. The detection rating was assigned as D=9, reflecting the absence of dedicated online detection or diagnostic mechanisms for voltage reference drift. In practice, such failures are difficult to detect without specialized testing equipment, and their effects may only become apparent through long-term data deviations. Those three values result in the highest RPN of 162. Similarly, the microcontroller (MCU), as the main control chip of the circuit, has a short-circuit failure mode caused by electrostatic discharge (ESD) surges or power supply overvoltage/overcurrent. Such failure may lead to device overheating, permanent damage, or loss of function, then s was rated as 8. The current preventive design incorporates a fuse, resulting in a low occurrence frequency of 2. However, the short-circuit failure mode typically require specialized diagnostic equipment for identification and cannot be detected through normal operation or software

Table 3. Detection evaluation criteria of DFMEA [8].

Detection Opportunity	Evaluation Criteria	D
No Opportunity	No current design detection; failure cannot be detected or analyzed	10
Undetectable at Any Stage	Weak design analysis and detection capability; significant differences between simulation analysis (EDA, CAE, etc.) and actual conditions	9
Minimal	Failure mechanism and mode can only be determined through simulation analysis (EDA, CAE)	8
Very Low	Failure mode and mechanism can be located based on input principles, drawings, data, and experience	7
Low	Unobvious phenomena (imaging quality, noise, etc.) exist; more than one failure mode can be located	6
Moderate	Unobvious phenomena (imaging quality, noise, etc.) exist; one failure mode can be located	5
Slightly High	Failure mechanism and mode can be discovered or inferred through certain failure physics and diagnostic algorithms	4
High	Obvious phenomena (sound, light, sensor monitoring, etc.) exist; more than one failure mode can be accurately located	3
Very High	Obvious phenomena (sound, light, sensor monitoring, etc.) exist; one failure mode can be accurately located	2
Detection Unnecessary	Failure mechanism and mode will not occur due to the adoption of a series of design schemes (design prevention, standards, and materials)	1

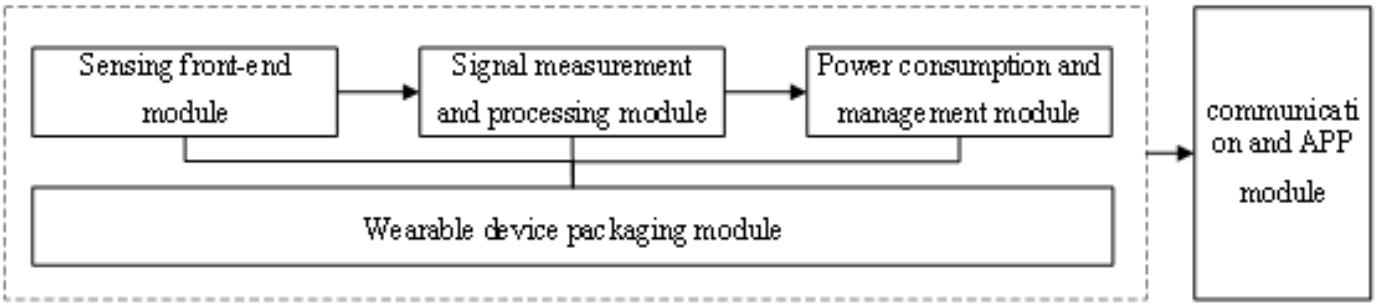

Figure 1. Modular components of non-invasive CGM.

monitoring, then the detection rate reaches 9.

These high-risk failure modes reveal critical design limitations related to electrical robustness, adaptability to user variability, and fault detectability. Addressing these issues through targeted design improvements is therefore essential for enhancing the overall safety and reliability of the CGM system.

3.3 Improvement Measures

Based on the DFMEA results, improvement measures were formulated and implemented for the identified high-risk failure modes. The improvement strategy focuses on three complementary aspects: reducing the occurrence probability of failures, mitigating their potential consequences, and enhancing failure detectability through improved design and diagnostics. The updated DFMEA ratings after implementing these measures are presented in Table 5.

For failure modes involving excessive or insufficient output current from the current source, a closed loop feedback control strategy was introduced. Specifically, the output voltage is dynamically adjusted according to the measured skin impedance. This design improvement reduces the likelihood of current deviation caused by impedance variability. As a result, the occurrence rating reduced from 3 (low) to 1 (very low), while detectability changes from 5 (average) to 3 (high). The corresponding RPN is reduced from 135 to 27 (an 80% reduction). This decrease demonstrates that impedance-aware current regulation effectively mitigates both safety risks and functional degradation associated with iontophoretic sampling. For the failure mode related to MCU short circuits, additional protection measures

Table 4. DFMEA Evaluation Results for Identified Failure Modes(selected).

No.	Component	Function	Failure Mode	Failure Cause	Failure Consequence	S	Current Prevention Design	O	Current Detection Design	D	RPN	Ranking
1	Current Source	Provide driving current for iontophoretic sampling	Output current too high or too low	Significant individual differences in user's skin impedance	Too high: Skin irritation or burns; Too low: Insufficient interstitial fluid extraction, leading to deviations in detection signals	9	Current upper-limit protection	3	Software monitoring	5	135	3
2	Microcontroller Unit (MCU)	Act as the main control chip of the circuit	Short circuit	Electrostatic Discharge (ESD) impact or power supply overvoltage/ overcurrent	Device heating and damage	8	Addition of fuse	2	-	9	144	2
3	Voltage Regulator	Provide a constant voltage source	Inaccurate output voltage	Impact of power supply fluctuations or external electromagnetic interference	Drift of ADC and analog front-end reference, leading to decreased measurement accuracy	6	Addition of filter capacitor	3	-	9	162	1

Table 5. Updated DFMEA ratings and RPN values after reliability improvements(selected).

No.	Component	Function	Failure Mode	Failure Cause	Failure Consequence	S	Current Prevention Design	O	Current Detection Design	D	RPN	Recommended Measures	Implemented Measures	Revised Severity Rating	Revised Frequency Rating	Revised Detection Rating	Revised RPN
1	Current Source	Provide driving current for iontophoretic sampling	Output current too high or too low	Significant individual differences in user's skin impedance	Too high: Skin irritation or burns; Too low: Insufficient interstitial fluid extraction, leading to deviations in detection signals	9	Current upper-limit protection	3	Software monitoring	5	135	Add closed-loop feedback control	Adjust voltage according to impedance	9	1	3	27
2	Microcontroller Unit (MCU)	Act as the main control chip of the circuit	Short circuit	Electrostatic Discharge (ESD) impact or power supply overvoltage/ overcurrent	Device heating and damage	8	Addition of fuse	2	-	9	144	Improve protection and power transient suppression	Add TVS diodes at I/O ports and enhance power transient suppression	4	1	9	36
3	Voltage Regulator	Provide a constant voltage source	Inaccurate output voltage	Impact of power supply fluctuations or external electromagnetic interference	Drift of ADC and analog front-end reference, leading to decreased measurement accuracy	6	Addition of filter capacitor	3	-	9	162	Improve PCB layout	Enhance anti-electromagnetic interference (EMI) design for key traces	6	1	9	54

were implemented by incorporating transient voltage suppression (TVS) diodes at critical I/O ports and strengthening power transient suppression. Consequently, the occurrence rating decreases from 2 to 1, while the severity rating is reduced from 8 to 4, leading to a reduction in RPN from 144 to 36. For failures related to inaccurate voltage output of the voltage regulator, design optimization was carried out by enhancing the electromagnetic interference (EMI) immunity of key circuit traces. The occurrence rating decreases from 3 to 1, and the RPN drops from 162 to 54. This result indicates that EMI-oriented design optimization is an effective means of controlling voltage stability-related risks in CGM systems.

Overall, the comparison between pre- and post-improvement DFMEA results demonstrates that the proposed design measures effectively reduce the risk levels of critical failure modes. These improvements enhance the electrical robustness, adaptability, and reliability of the non-invasive CGM system, thereby contributing to safer and more reliable long-term glucose monitoring. It should be noted that, in addition to the representative failure modes discussed above, other identified failure modes were

also evaluated and corresponding improvement measures were formulated and implemented. However, for clarity and conciseness, only selected high-risk and representative cases are presented in detail here.

4 Conclusion

This paper applies the DFMEA method to analyze failure risks in non-invasive CGM systems by decomposing the system into five functional modules and evaluating identified failure modes in terms of severity, occurrence and detection. For the identified high-risk failure modes, namely current-source output deviation and regulator voltage inaccuracy, design improvements are implemented. Specifically, an impedance-based voltage adjustment strategy and enhanced electromagnetic interference (EMI) immunity of key circuit traces are introduced. These measures reduced the RPN values from 135 to 27 and from 162 to 54, respectively.

Future research will focus on long-term tracking studies to collect large-scale, extended-duration operational data from non-invasive CGM systems. Such data would support a more comprehensive validation of the optimized system design and further ensures its long-term reliability in practical applications.

Data Availability Statement

Data will be made available on request.

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Conflicts of Interest

The authors declare no conflicts of interest.

Ethical Approval and Consent to Participate

Not applicable.

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