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RESEARCH ARTICLE

Design and Implementation of a Medical Device Data Dictionary System Based on Software Engineering Theory

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ABSTRACT Objective: Based on software engineering principles, we designed and implemented a medical device data dictionary system that aligns with data integration and industry standards to fulfill the data management needs of medical institutions and healthcare professionals. Materials and Methods: Utilizing the web-based framework alongside open-source technologies such as Spring Boot, Spring Security, Apache MyBatis, Vue, and Element UI, along with database technologies such as MySql, MongoDB, and Redis, we analyze the basic elements of medical device data dictionary system and incorporate layered architecture technology, design the system architecture, functional workflows and database model required for the dictionary system, and conduct professional testing and trial evaluation of the system. Results and Analysis: In this study, we constructed a web-based open medical device data dictionary system that supports front-end and back-end operations. Using a ventilator as a sample for non-integrity assessment, the results of the system utility test showed that the system is functionally complete, satisfies the compatibility requirements of mainstream browsers and poses no significant risks or vulnerabilities to system operation. Conclusion: A medical device data dictionary that characterizes life cycle usage attributes based on their structural and functional properties was constructed. It provides a unified and standardized base for the management and analysis of medical device data, and helps realize the interaction and exchange of medical device data between disparate medical information systems.

INDEX TERMS Medical devices, data dictionary, software engineering theory, web-based framework.

I. INTRODUCTION

The management of medical equipment in medical institutions faces several challenges. The diversity of device types, complex specifications, and inconsistent coding practices contribute to difficulties in device management, directly and indirectly affecting the efficiency of device administration and patient safety [1], [2], [3]. Additionally, because of the code description specifications, data sources, and data structures of different medical organizations [4], the primary data systems established by medical institutions are biased toward device data dictionary applications [5] and suffer from the problem that data transmission efficiency and accuracy are difficult to guarantee. Therefore, it is necessary to construct a universal data integration environment and a medical device data dictionary system that aligns with industry specifications, which can be used to facilitate integration with other systems and enable data sharing among various healthcare institutions to solve the problems of data chimneys and the nonuniformity of specifications among systems.

There are fewer studies related to medical device data dictionaries, and this study draws on the success of data

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dictionary construction in other mature fields. Observational Health Data Science and Informatics (OHDSI) has constructed a common data model framework for multi-party data exchange that focuses on standardized patient diagnosis and treatment data descriptions, a framework that does not directly address the construction of medical device data dictionaries [6]; Singh et al. compiled a neonatal intensive care unit (CCU) data dictionary that effectively captures and describes patient data in the CCU environment [7]; Rashid et al. further advanced the semanticization of data dictionaries by designing an innovative semantic data dictionary for the biomedical domain, which not only annotates the dataset columns and their values, but also digs deeper and expresses the tacit knowledge behind the data fields by fusing the best-practice vocabularies and ontology concepts, enriching the data's connotation and comprehensibility [8].

However, while the aforementioned data dictionaries are each distinctive and effective, they focus exclusively on their specific application areas and fail to comprehensively cover the unique and complex field of medical devices, lacking in-depth reflection of the unique attributes and lifecycle management requirements of medical devices.

Therefore, this study is grounded in the intrinsic characteristics of medical devices and their practical management needs, which are closely aligned with the latest standards and regulations within the industry. It systematically collects and refines the core data elements of the medical device data dictionary, which encompasses attributes across three dimensions: structure, function, and device usage. By employing a hierarchical architecture design technique, an information feature mapping system for the medical device data dictionary has been established. This aims to comprehensively and accurately represent various attributes of the devices and their usage status throughout their entire lifecycle, providing a solid data foundation and technical support for the management, maintenance, and optimization of medical.

II. MATERIALS AND METHODS

Based on software engineering theory, this study divides system design into three parts: the first part focuses on the essential elements of the data dictionary for system construction requirements; the second part concerns the system architecture, functional processes, and database design; and the third part involves system implementation and relevant testing and evaluation.

A. DATA DICTIONARY BASIC ELEMENTS

In accordance with industry standards for medical device technical parameters, health information metadata construction guidelines and the practical requirements for the development, maintenance, and application of data dictionaries [9], [10], the basic elements of the data dictionary are categorized into dictionary construction tools, dictionary application tools, and dictionary system infrastructure.

(1) Dictionary Construction Tools: These tools primarily refer to dictionary editing tools used to define the properties and relationships of different device data dictionaries. They serve designers, reviewers, and managers of data dictionaries and are applied in scenarios such as dictionary definitions, reviews, and updates.

(2) Dictionary Application Tools:These tools mainly consist of dictionary browsers that enable retrieval, display, and export services for data dictionaries based on multiple conditions.

(3) Dictionary System Infrastructure: This refers to the software and hardware environment used for system development, testing, or deployment, including software tools, servers, networks, and other resources required for development and testing.

(4) The response time of the system under regular operation is controlled within 5s, and the system supports 200 concurrent users (according to the actual needs of current users).

B. SYSTEM DESIGN

1) SYSTEM ARCHITECTURE DESIGN

Following architectural style theory [11], the system architecture is divided into four layers: data layer, infrastructure layer, business logic layer, and user interaction layer. By clarifying the responsibilities and boundaries of each layer, the complexity of the system can be reduced, improving the development efficiency and quality of the system (Fig. 1).

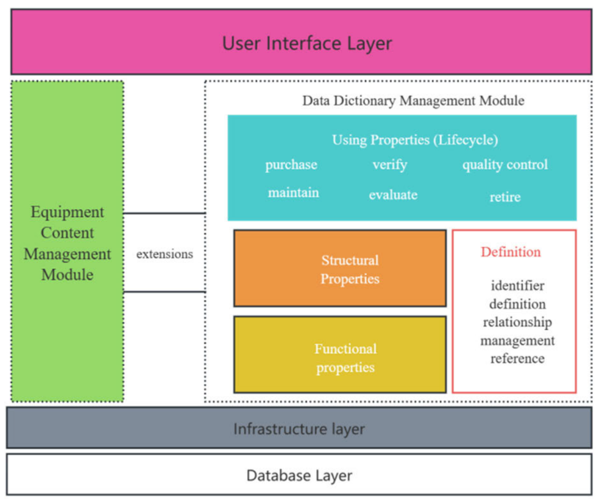

FIGURE 1. Systems architecture model.

(1)The data layer is responsible for data storage and maintenance. It comprises relevant dictionary data and system logs, stored using relational and NoSQL databases [12], and provides functionalities for data creation, modification, deletion, and retrieval.

(2) The infrastructure layer handles database access, transaction management, logging, permission control, and data monitoring. It is the technical core of the architecture, employing connection pooling for data layer connectivity [13], annotations or mapping techniques for data persistence operations [14], aspect-oriented techniques for logging

(operational, error, and system logs) and service management [15], and Role-Based Access Control (RBAC) for authentication and access management [16].

(3) The business logic layer handles core processing for the medical device data dictionary, including modules for device management, dictionary data unit management, extended connectors [17], path permission management, and operation menu management. It is responsible for validation, transformation, and calculations related to data processing, implementing mappings, definitions, and relational descriptions of dictionary data elements.

(4) The user interaction layer facilitates the browsing and searching of the medical device data dictionary. It employs a component-based, declarative programming model [18] and interacts with users via a web-based interface [19], offering multicondition browsing, searching, exporting, and maintenance based on dictionary entries.

The layers in the system architecture are independent, with each layer having input and output interfaces. The upper layers directly regulate the data information of the lower layers, which serve as information sources for the upper layers. Following the Separation of Concerns (SoC) principle, a layered architecture organizes similar system operations into the same layer, achieving loose coupling between layers [20].This design enhances maintainability, extensibility, and flexibility while reducing complexity and development costs and ensuring data storage security, integrity, reliability, and efficient data access.

2) SYSTEM FUNCTIONAL PROCESS DESIGN

The system's functional process design followed the "definition-review-search and browse" functional requirements (Fig. 2).

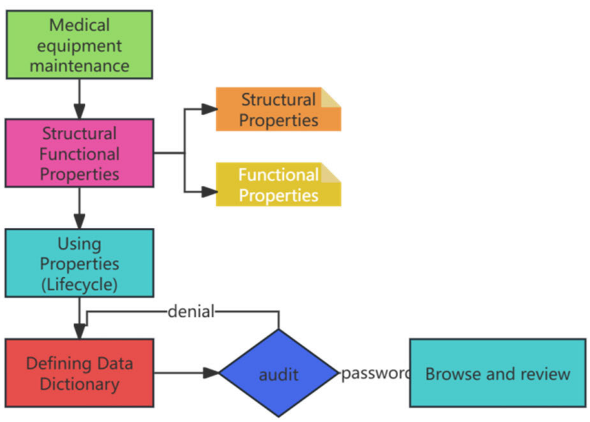

FIGURE 2. System function flowchart.

Dictionary designers summarize dictionary definitions based on equipment data dictionary elements and map structural properties, functional properties, and usage properties of equipment; dictionary data administrators review, evaluate, and maintain dictionary data; Normalized and standardized dictionary entry searching and browsing functions based on users' equipment management needs.

3) SYSTEM DATABASE DESIGN

The system database design involves categorizing and summarizing data dictionary elements to form basic dictionary entries and determining attribute ownership. Secondly, establish logical relationships between system entities and clearly define their dependencies. (e.g., the structural-functional properties of the equipment may represent multiple usage properis, indicating a 1: N relationship); Finally, Redundant logical relationships are optimized and merged, and database tables and fields are designed to form the physical structure of the database. As shown in Fig. 3, the system utilizes the PowerDesigner tool to construct database conceptual, logical and physical structures based on the 3N paradigm theory of database.

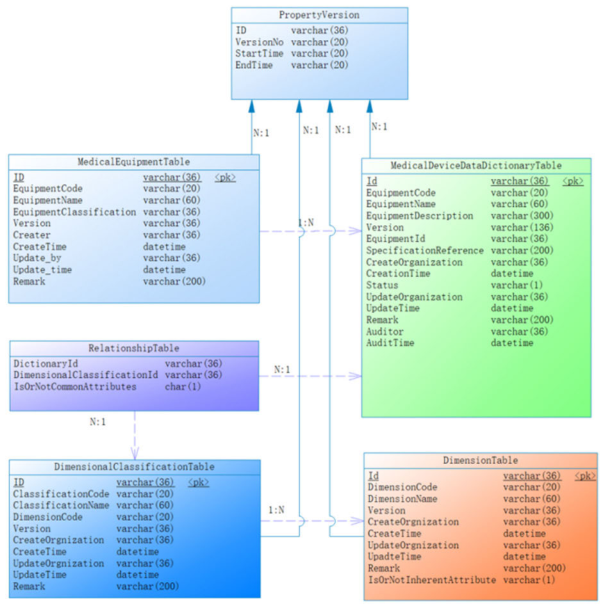

FIGURE 3. System database model.

C. SYSTEM IMPLEMENTATION

1) TECHNICAL IMPLEMENTATION OF THE DATA DICTIONARY SYSTEM

The system uses JAVA as the programming language, employing IDEA and HBuilderX as integrated development environments for the front-end and back-end, respectively. It applies a waterfall development model, while data loading is realized through the system (Fig. 4).

(1)The database layer utilizes the open-source relational database (e.g.,Mysql and MongoDb [21]) to store structured business data and unstructured log data. The Key-Value database Redis is used for data caching [22].

(2)The infrastructure layer utilizes Java Spring Boot [23] and Spring Framework [24] to conduct framework management, Spring Security [25] for access control and user

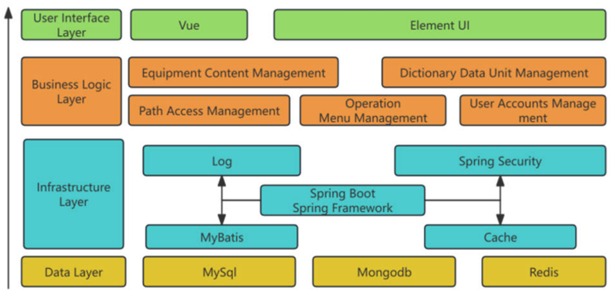

FIGURE 4. System technology platform implementation diagram.

authentication, and Apache MyBatis [26] along with Alibaba Druid [27] for object persistence and data access.

(3) The business logic layer includes components of medical equipment intrinsic components and dictionary data unit components. Each component is divided into multiple entity entities (dictionary definitions, structural properties, functional properties, and usage properties). Specific business requirements are implemented in Services, including mapping services for structure, function, and usage attributes, dictionary management services, and medical device management services. These services are exposed to the user interaction layer through REST-style Spring Controllers [28].

(4) The user interface layer is built using the VUE and Element UI open-source frameworks [29], encapsulating logic (JavaScript), templates (HTML), and styles (CSS) in the same file [30]. Interaction between pages is achieved through VUE's components such as routing, state, and API, while interaction with users is facilitated through Element UI components.

The system is deployed on three servers, with two application servers and one database server. The deployment of the application servers follows a front-end and back-end separation approach, where Nginx is used for the front-end deployment and Tomcat is used for the back-end. This deployment strategy enhances system performance and scalability while ensuring clear separation and independent development between the front and back ends [31] (Fig. 5).

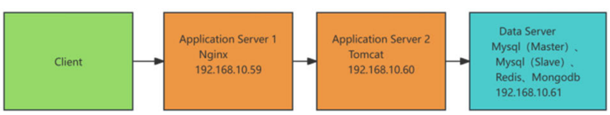

FIGURE 5. System deployment diagram.

2) SYSTEM TESTING AND EVALUATION

This study was conducted based on the actual operational environment of the system, with three servers configured using listed parameters for CPU, memory, storage, and operating system (Table1).

In order to ascertain whether the system is capable of meeting the demands of multi-user concurrent operation in practical application scenarios, and to provide a comprehensive evaluation of the operational effectiveness of the system

TABLE 1. System test environment parameter configuration.

Environment	Configration
CPU	Intel(R) Core(TM) i5-1035G1 CPU
RAM	DDR4, 2933MHZ, 16GB RAM
Storage	1TB SSD
Operating System	CentOS 7.9
TestTool	JMeter 5.6.2、BurpSuite V2022.3.8、Namap V7.94、Sqlmap V2023.09、Xenu 1.3.8
Web Application	Nginx 1.20.2、Tomcat 9.0.1
Database	MySQL 5.7、MongoDB 6.0.11

under high-intensity loads, a series of tests were conducted in accordance with the specifications set out in the computer software testing manual [32] and the characteristics of the system. The tests were designed to assess the functionality, compatibility, performance and security of the system, and were carried out in real environments.

a: SYSTEM FUNCTIONAL TESTING

The primary objective of functional testing is to ascertain whether the system functions in accordance with the design requirements. To achieve this, testers utilize the requirement specification as the baseline and employ strategies such as equivalence classes, boundary values and functional diagrams to devise test cases [33]. They focus on evaluating the completeness of functions, proper display of features, input type validation, form submission processes, data preservation integrity, and the presence of any broken links as their testing items.

b: SYSTEM COMPATIBILITY TESTING

System compatibility testing aims to verify the effectiveness and stability of system functions in different environments [34], Compatibility testing for web-based systems involves two main aspects: page rendering and functional adaptation. Using mainstream browsers as the test cases, the test items include function, form submission, interface display and response speed is normal, etc. [35].

c: SYSTEM PERFORMANCE TESTING

In this study, the industry-recognized JMeter performance testing tool [36] was used to evaluate the performance of the system. Test metrics include the number of concurrent users, average response time, error rate, transactions per second and system resource utilization rate [37]. The test content covers queries related to medical device data dictionary entries, categories, properties, management, and other related data. A typical test case involves gradually increasing the number of users sending requests (every 5 seconds, 10 new users are added, with each user sending 100 requests) until the system reports an exception.

d: SYSTEM SECURITY TESTING

System security testing ensures that the system can withstand external threats and protect internal data from unauthorized access. External penetration scanning of the system is conducted using professional security tools such as BurpSuite [38], Nmap [39], and Sqlmap [40]. Testing items include identity authentication, application access control, cross-site scripting (XSS), cross-site request forgery (CSRF), SQL injection, and sensitive information leakage. Testing follows a structured approach, including information gathering, vulnerability scanning, authentication attacks, and exploitation attempts [41].

e: SYSTEM PRACTICALITY TESTING

A ventilator is selected as a sample for practical nonintegrity testing of the system. Dictionary designers create a dictionary with 157 entries (54 functional properties, 47 structural properties, 56 usage properties) based on the basic elements of the data dictionary. These entries are used in budgeting and bidding scenarios to evaluate the system's practicality. The user may access and retrieve dictionaries that have been reviewed and approved by domain experts.

III. RESULTS AND ANALYSIS

A. MEDICAL EQUIPMENT DATA DICTIONARY SYSTEM

The medical equipment data dictionary system is divided into two parts: front-end application tools and back-end processing tools. The front-end includes functions such as dictionary search, dictionary browsing, and dictionary export. The back-end comprises the equipment dictionary maintenance unit, structure and function property maintenance unit, usage property process maintenance unit, usage property scene maintenance unit, and equipment property definition unit. Based on different user roles, corresponding permissions are set for dictionary designers, dictionary administrators, and system administrators (Fig. 6).

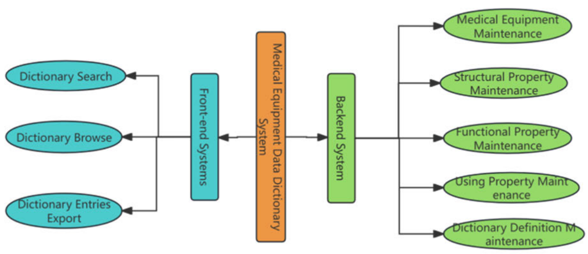

FIGURE 6. System functional diagram.

Dictionary designers have ''general'' access to the device dictionary and can perform administrative operations on medical device coding categories. Dictionary administrator has the authority to audit the device dictionary and is responsible for the standardized audit of dictionary entries. The system administrator is responsible for assigning account privileges and configuring related parameters.

B. SYSTEM TESTING AND VALIDATION RESULTS AND ANALYSIS

(1) The results of the system functionality test show that the system has complete functionality, no crashing program errors, and no isolated dead links. The system's functionality meets the maintenance and application requirements of the ventilator data dictionary.

(2) System compatibility testing indicates that when operated by a single user, all functional interfaces display, form submissions, and response speeds are normal. No compatibility issues have been detected with mainstream browsers. This demonstrates that the system passes the mainstream browser compatibility test.

(3) The results of the system performance tests demonstrate that the average server response time increases gradually in line with the number of users. Furthermore, the response time for the dictionary entry lookup function is the longest due to the fact that it sends and receives the largest amount of data.

As the quantity of data transmitted and received by the network increases, the response time also increases in a gradual manner. Upon reaching 300 users, 90% of requests exhibit the longest response time of 4.97 seconds, while the interface request is error-free, indicating optimal concurrency within the system and adherence to the system performance requirements. Upon reaching 600 users, the average response time reaches 8.87 seconds, with no interface errors. At 900 concurrent users, 90% of interface requests report errors (3 no HTTP response) (Table 2).

The number of concurrent users in this system test is increased gradually until it reaches 926. At this point, the interface request is reported as an error (3 no HTTP response), which represents the maximum concurrent users supported by the system (Fig. 7). The average response time for dictionary entry retrieval is the longest, with a maximum time of 11 seconds (Fig. 8). The number of transactions per second of the server is essentially stable (maintain around 150), with no error transactions occurring (Fig. 9). The resource utilisation of the server is within an acceptable range after stabilization (CPU 80%, memory 65%) (Fig. 10).

(4) The purpose of system security testing is to prevent data leakage and unauthorized access. This study uses a variety of professional security tools, including BurpSuite, Nmap, and Sqlmap to conduct external penetration testing of the system. There were one high-risk vulnerability, three medium-risk vulnerabilities, and one low-risk vulnerability were identified through the testing (Table 3).

There are no security risks such as SQL injection or application access control. To address the high-risk vulnerability (weak password vulnerability), a strong password policy is adopted, requiring passwords to be at least 8 characters long and contain letters, numbers, and special symbols. For low to medium risk vulnerabilities, measures such as mandatory

TABLE 2. **Performance test data volume statistics.**

Request	Executions			Response Time(ms)			Network(KB/sec)	
Label	Errors(300)	Errors(600)	Error(900)	90th pct(300)	90th pct(600)	90th pct(900)	Received	Send
Dictionary Entry Search	0	0	1	4968.9	8087.8	14145.7	217.04	10.87
Medical Device Category Search	0	0	1	3130	4943.8	9303	86.7	6.93
Using Property Flow Query	0	0	0	598	775	2046	109.08	7.91
Using Property Scenario Queries	0	0	1	597	766.9	2021.9	27.33	9.18

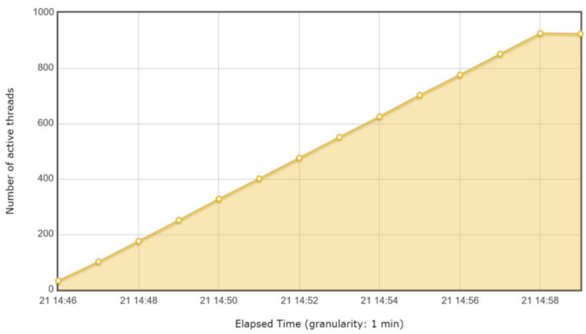

FIGURE 7. **Concurrent user test curve.**

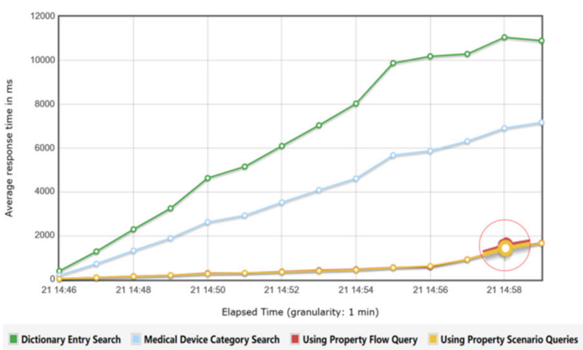

FIGURE 8. **Mean response time for system acquisition data illustrate on a comparison curve.**

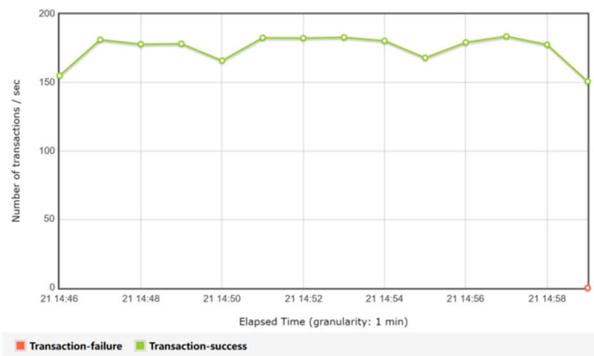

FIGURE 9. **System TPS curve.**

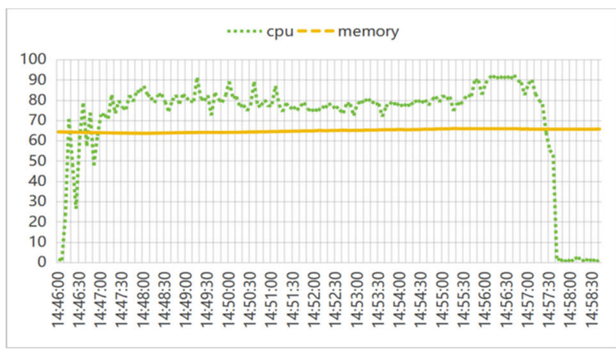

FIGURE 10. **System CPU and memory utilisation distribution curve.**

refreshing of the verification code after login failures, vague error messages, encrypted transmission of information, and hiding server-related information are implemented to meet the system's security requirements. The program was retested after the fix and no vulnerabilities were found.

(5) System usability validation: The system undergoes a one-month usability test using a ventilator as a sample. The ventilator has a total of 157 dictionary properties (Table 4), successfully simulating procurement and bidding scenarios. The results indicate that the front-end and back-end data dictionary system can meet the requirements for the creation, maintenance, retrieval, and browsing of the data dictionary, and the system operates stably.

IV. DISCUSSION

A medical equipment data dictionary defines and describes the characteristics of medical device properties. It is a collection of data that describes the characteristics of data properties, consisting of dictionary entries [42]. Standard data encoding and description form the foundation of data sharing and interconnectivity across platforms. Through the construction of a hospital's primary data platform, Bao et al. [43] achieved standardized coding for patients, medical projects, finances, and fixed assets within the hospital and realized the unified management of information within the hospital. Liang [44] has successfully enabled data sharing and interconnectivity among various systems within the hospital by

TABLE 3. System security test results.

Test Tools	Test Items	Vulnerability Name	Level	Potential Impact
BurpSuite	Sensitive Information Leak	Weak Passwords	High	Attackers can directly log into the application using weak passwords
BurpSuite	Authentication	Captcha Bypass	Medium	Attackers can exploit this vulnerability to continuously attempt to log in using usernames and passwords.
BurpSuite	Authentication	Username Guessing	Medium	Attackers can get the correct username
BurpSuite	Sensitive Information Leak	Plaintext Transmission	Medium	There's a risk that personal identification information could be intercepted during online transmission.
BurpSuite	Sensitive Information Leak	System component information leakage	Low	Attackers could potentially exploit leaked system component version information for subsequent attacks.
Nmap	Application Access Control	No problems found		
Sqlmap	SQL Injections	No problems found		

establishing a primary data platform that standardizes the coding and description of patients, departments, and medications. In this study, a national unified medical equipment standard coding method is adopted, and the definition of the data dictionary is divided into identification, definition, relationship, management organization, and reference specifications based on the national health information basic datasets specifications [45]. This design facilitates the sharing and exchange of medical equipment data between different medical institutions.

Focusing on the in-depth analysis of the essential content, fine structure, and intricate relationships of medical devices, this research has successfully designed and implemented a comprehensive and efficient medical device data dictionary description system. In order to further optimize the system architecture and enhance the system's cohesion and scalability, we have breakthroughly reconfigured the traditional three-tier architecture into a four-tier architecture model, which greatly enhances the system's reusability and ease of testing and maintenance.

The modeling of the data dictionary is abstracted into three core modules: the device connotation management module, the data dictionary unit management module, and the extension connector as a bridge. As the cornerstone of the system, the Device Connotation Management Module focuses on the standardization of medical device coding and the detailed elaboration of inter-device relationships, which injects rich semantics of device attributes into the data dictionary and greatly enriches the connotation and expressiveness of the data. The Data Dictionary Unit Management Module focuses on mapping the unique attributes of medical device data elements, which accurately captures and represents the differentiated characteristics of different medical devices by finely dividing the three dimensions of structural attributes, functional attributes, and usage attributes. In particular, the introduction of the usage attribute component complements the scenario-based semantics of the first two components to effectively reduce vagueness and ambiguity in the descriptions. The generic attribute description uses the attribute definition components to ensure the commonality and consistency of information among different types of medical devices, and achieves the comprehensive coverage of content and clear definition of the structure of data elements. All these help to improve the accuracy and practicality of the data dictionary. As a key link in the system architecture, the extension connector skillfully connects the device content management module and the data dictionary unit management module, clearly defines the interdependence and data interaction mechanism between them, and ensures the smooth transfer and efficient integration of information within the system.

Although there is no lack of successful medical data dictionary systems in the current medical field, such as 3M Healthcare Data Dictionary [46], which divided the data dictionary description into three major sections, namely information model, vocabulary, and knowledge base, and provided a standardized data representation for the fields of medical diagnosis, diagnostic and treatment equipment management, and so on. However, the system is still lacking in in-depth mining and detailed description of medical device data characteristics. In addition, although the HL7 interface protocol plays an important role in standardizing medical information transmission and ensuring smooth communication of information interfaces [47], there is a lack of specific guidance on how to standardize the description of content, which poses a certain challenge for practical applications. Therefore, the medical device data dictionary description system constructed in this study not only fills the gaps in the existing systems in the description of medical device data characteristics, but also opens up a new way for the

TABLE 4. Ventilator dictionary procurement and bidding entries (partial).

Dimensions	Indicator name	Description of indicator
structural properties	AC-DC power supply module	A device that converts alternating current to direct current. It usually consists of a transformer, rectifier and filter.
	Cell	A device that converts chemical energy into electricity and stores it
	Battery transfer board	A converter used to connect different types or specifications of batteries to devices.
	DC-DC power panel	A circuit board for DC (DC) power conversion. It can convert one DC voltage to another different DC voltage to meet the needs of a particular device or system.
	Power module cooling fan	A heat dissipation device used for the power module
	Mother blank	An important part of the computer hardware, which is the basic circuit board to connect and support other hardware devices
	Main control panel	The center or main circuit board of the electronic system, which provides engagement points for the connection and control of different devices.
	Alarm light board	A device with integrated sound and visual alarm function for various occasions requiring warning or notification.
	Touch screen control board	A circuit board that allows the user to control the device by touch
	Key-button and encoder board	Input devices used to realize human-computer interaction.
	...	...
functional properties	Inspiration flow oxygen concentration	Percentage by volume of oxygen in the patient's inhaled gas mixture
	Tidal volume	The volume of gas inhaled or exhaled by the patient at a time, and in the case of a ventilator, the volume of the gas mixture delivered by the machine to the patient at a time
	Respiratory rate	Number of times per minute that gas is delivered to the patient in a controlled, assisted, or voluntary manner
	Synchronized intermittent command ventilation respiratory rate	In SIMV mode, the number of times per minute the patient is ventilated on command according to preset parameters.
	Inspiration time	Interval between onset of inspiration and onset of expiration, including inspiratory plateau time
	Inspiratory/expiratory time ratio	Ratio of inspiratory time to expiratory time
	Pressure rise time	The time it takes from the start of air delivery to reach the preset airway pressure.
	Positive end-expiratory pressure	Values of end-expiratory airway pressure
	Inspiratory pressure level	In pressure control or pressure support mode, the ventilator delivers air to the patient at this set pressure
	Stress support level	Preset airway pressures provided by the ventilator are used to assist the patient's voluntary respiratory efforts.
	High level of pressure	The ventilator is maintained at a relatively high pressure state to support the patient's inspiration and gas exchange.
	...	...

standardization and intelligent development of medical data management through the innovative four-layer architecture design and fine module division.

Due to the complexity and professional nature of medical equipment, there has been limited research on medical equipment data dictionaries [48]. This study primarily builds on research findings from other industries to enrich the study of data dictionaries in the field of medical devices. Practicality testing was conducted using only ventilators, presenting certain research limitations. Future research should evaluate the performance of the system under different equipment loads to broaden the application and assessment of device dictionaries.

The core functionality of a data dictionary system lies in its dictionary-building tools, and various construction methods exist. RxNav, for instance, is a drug dictionary information browsing tool built for standards like RxNorm, RxTerms, and NDF-RT, catering to different regional query requirements [49]. It is designed to meet the query requirements of various regions. Liu et al. [50] has created an open-source standard data dictionary for neonatal intensive care units using EXCEL, although this approach may lead to human errors and data redundancy. Similarly, Singh et al. [7] has suggested a design for a health information data dictionary management system based on a Web approach to address hospital data standardization issues, but this system lacks an operational construction tool. Given the absence of dedicated construction tools for medical equipment dictionaries and the complex and multi-stakeholder nature of the task, which requires collaborative development, this study adopts a web-based approach to building a medical equipment data dictionary tool.

The Health Information Standards Platform focuses on developing a comprehensive and unified standards system [51]. However, it does not provide detailed descriptions of the content of medical device data dictionaries, nor does it reflect the intrinsic characteristics of medical devices. Considering these features, this study further subdivides the data dictionary unit management module into structural property components, functional property components, usage property components, and property definition components. The structural properties and functional properties of components focus on the structural and functional aspects of a medical device, providing information about its working principles, construction, and capabilities. The usage property components emphasize the operational and usage characteristics of the equipment, offering guidance on its proper use in practical scenarios. The property definition component defines and explains each property explicitly, such as the data type and data range. This study's business logic layer represents the usage property's description of equipment lifecycle scenarios, and the property definition relies on structural, functional, and usage properties to achieve standardized descriptions of medical equipment properties. With this segmented component design, the medical device data dictionary system is easier to maintain and use. Users can select different components to view or edit device information according to their needs, ensuring more efficient and accurate data management and updating. In addition, this structure also helps to improve the scalability and flexibility of the data dictionary system, adapting to the changing needs of different healthcare organizations or device manufacturers.

In terms of system architecture design, with the advancement of development technologies and the emergence of various development frameworks, front-end and back-end separated layered architectures have increasingly become mainstream development frameworks that can improve the efficiency of development and system performance [52]. Kang et al. [53] designed and implemented a student information management system based on a front-end and back-end separated architecture, aiming to reduce the coupling between system modules. To improve development efficiency and system performance, this study adopts a Web-based front-end and back-end separated development framework, extending the two-layer architecture to four layers: "data layer - infrastructure layer - business logic layer - user interaction layer," which handle data storage, technical services, data processing, and data usage, respectively. This architecture not only supports the expansion of data dictionaries for different medical equipment but also facilitates the separation of technical and business concerns, reducing dependencies between modules and further enhancing the system's security, stability, and flexibility.

Regarding technical implementation, the system in this study uses Spring Boot as the core technology framework, with MySQL as the relational database and MongoDB as the non-relational database for data storage. To enhance the data access speed, the Key-Value database Redis is utilized for data caching [54]. Spring Boot, as a mainstream Java Web development framework, offers strong integration and easy deployment [55]. MySQL, a multi-user and multi-threaded database, is characterized by its small size, fast speed, and low cost [56]. MongoDB, a distributed file storage database, supports complex data type storage and massive information queries [57].

In terms of system security, Wang et al. [58] proposed effectively mitigating security risks associated with data acquisition, transmission, and storage in cloud computing environments through methods such as identity recognition, access control, data backup, and data encryption. Considering the system's architectural characteristics and data security risks, this study employs security measures such as HTTPS data encryption transmission, identity authentication access control, database hot backup, log auditing, and security rate limiting, along with modern cryptographic algorithms, to proactively protect the system and reduce the risk of data leakage.

This system focuses on the storage and management of data related to medical device data elements, strictly adheres to data processing principles, explicitly does not include personal health data, ensures the compliance and ethics of data processing, and at the same time strictly adheres to the latest technical specifications in the field of cybersecurity to ensure the security of data transmission and storage. Considering the various user roles served by the system and the differences in the access needs and scope of authority of different users to data resources, the Role-Based Access Control (RBAC) security model has the characteristics of usability, expressiveness, extensibility, and flexibility [59], and is able to meet the security management needs of this system, so the RBAC policy is chosen to implement the authentication and authorization management of the system.

For system evaluation, Fasolino et al. [60] have proposed that system testing based on the Web should be divided into functional testing and non-functional testing, with the latter including security testing. Tiwari et al. [61] have conducted a comparative analysis of mainstream web performance testing tools, indicating that JMeter is more suitable for performance testing with large volumes of data. We chose JMeter, a powerful, flexible, and easy-to-use performance testing tool that can simulate concurrent multi-user requests and apply pressure to the system to measure the performance index of the system under various load conditions. The test scenarios cover data query operations in several key business scenarios, such as medical device data dictionary entries, classifications, attributes, management, etc., to ensure the comprehensiveness and representativeness of the test. This study assesses the system's functionality, compatibility, performance, and security through rigorous testing to ensure its stability and reliability. The results indicate that the system meets the requirements for data dictionary construction and application and is compatible with mainstream browsers. With the current hardware configuration, it is recommended to have an optimal concurrent user count of 300, with a maximum load capacity of 926 users, without any security risk vulnerabilities that affect system operation. To further enhance the system's load capacity, server resources can be increased, or load balancing techniques can be employed to improve concurrency [62].

Throughout the development and design process, it is essential to engage with medical equipment manufacturers, administrators, doctors, and technical personnel to gain a better understanding of user needs and make targeted improvements and maintenance to the medical equipment data dictionary system.

The medical device data dictionary system emerges as a pivotal tool for managing medical equipment, significantly enhancing the quality and efficiency of data integration, governance, analysis, and decision support. Given the continuous evolution of medical device technology and the dynamic nature of user requirements, it is imperative to periodically upgrade and maintain the system. Furthermore, collecting user feedback and incorporating improvement suggestions are crucial for the ongoing optimization of the system's functionality and performance. Future research directions include further refining system performance, expanding its application scope, and strengthening integration and interoperability with other information systems.

V. CONCLUSION

Guided by software engineering principles and closely aligned with industry standards and business needs, the system successfully establishes an open, web-based medical device data dictionary system tailored to the unique properties of medical equipment. This system provides a unified data dictionary description for various medical devices and offers comprehensive, efficient functionalities for data maintenance, review, retrieval, browsing, and export. Practical tests and verification results demonstrate that the system meets the actual requirements of medical institutions for a data dictionary system, exhibiting high stability and security. It facilitates data sharing and exchange among different medical institutions, thereby contributing to improved management efficiency and service quality in the healthcare industry.

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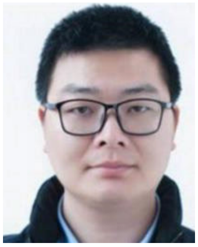

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