Improving the Input Information for Medical Software Requirements Specifications using Ontology-Based Intelligent Agent

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Abstract. The conducted analysis of known ontology-based intelligent agents (OBIA) showed that nowadays the task of the research and improvement of characteristics of input information for medical software requirements specifications (M-SRS) was not solved by the OBIAs. Also, they do not provide the quantitative assessment of the level of elaboration of the life cycle initial stages of medical software based on the analysis of specifications. So, the task of this study is the development of the OBIA for improving the input information for the formation of M-SRS. The scheme of the process of improving the input information for the formation of M-SRS using the OBIA is developed, and this intelligent agent (IA) is realized. This IA evaluates and improves the input information for the formation of the requirements specification for medical software. For the experiment, the developed OBIA used the specification of the requirements for real medical software of information and analytical system for accounting of therapeutic and diagnostic activities provided to the wounded during transportation, which was developed by one of the software companies in Khmelnitsky. During this experiment, the developed intelligent agent provided to improve the input information for the formation of the specification of requirements for the specified medical software, namely, IA provided the raising level of sufficiency of input information for determining the software quality in the M-SRS by 24%.

Keywords: Medical Software, Medical Software Requirements Specification (M-SRS), Ontology, Intelligent Agent (IA), Ontology-Based Intelligent Agent (OBIA).

1 Introduction

Today all human activity spheres, including medicine, use computer systems based on the software.

Today, in Ukraine, there is an acute problem of informatization of the healthcare industry. One way of solving this problem is the development of medical software, the successful implementation of which helps physicians to quickly receive new information on their speciality, provides them to accumulate, process and use information on disease histories of patients on a qualitatively new level, significantly increases the productivity of medical workers, increases the efficiency of use of healthcare resources, accelerates the integration of Ukrainian medicine into the European medical space [1-4].

All medical software is divided into: diagnostic software (integration of physical methods of radiation diagnostics and software), therapeutic software (integration of the software with artificial intelligence system with the purpose of simulation of human behavior regarding sensory information as a reflection of the external world), therapeutic and diagnostic software (saving, displaying data and knowledge, developing the algorithms for processing information for decision-making while solving a problem at medical or diagnostic stage), and information and analytical software (determining and planning all the resources of medical institution, which are necessary for therapeutic and diagnostic activities, and accounting in the process of providing the medical services) [1, 2].

Medical software is the critical application software, since its incorrect functioning can lead to [5]: human deaths (the infamous "deathly" radiation sessions using Therac-25, during which 6 patients received a lethal dose of irradiation due to incompleteness of the software requirements specification [6]), to the loss of patient's health (during the radiation therapy at the National Cancer Institute in Panama City, 28 patients were exposed to excessive irradiation due to the incorrect calculation of radiation doses by the software of Multidata Systems International [6]), or at least to the leaks of information about the diagnosis, disease and the patient's state of health. Therefore, the quality of medical software is one of the most important factors for its successful implementation and operation. However, in presence of many methods and tools, in the best specialists involvement in software design and development, success and quality of medical software are still dependent on developers' knowledge and experience.

A large number of errors is entered into the software at the stage of formation and formulation of requirements as a consequence of information losses, of the incompletion and difference in the understanding of the information needs and context. Particularly such information losses are substantial for software projects at the subject domains junction, i.e. precisely for medical software, because during the development of this software it is necessary to consider both standards for the software development and the subject domain standards (healthcare standards).

The life cycle of software development (including medical software) begins from the development of the set of requirements and the software requirements specification on their basis. The main sources of information during the formation of requirements for medical software are the customer's business requirements (describe the goals of the system, criteria for achieving goals, the key requirements for results and their priorities and constraints), subject domain requirements (healthcare, medicine), standards (both software engineering, and healthcare, medical standards), descriptions of the software developing and implementing process, etc. [7]. On the basis of the above input information, the M-SRS is created.

Consequently, the characteristics of the input information vastly determine the characteristics of medical software requirements specifications. If the input information is insufficient, inaccurate, ambiguous or contradictory, then there is a high probability that all these shortcomings will be reflected in the M-SRS. For ensuring the quality of medical software, *it is necessary to research and improve the input information with the purpose of identifying and solving the problems and disadvantages at the software life cycle initial stages*. In particular, it is necessary to assess the input information completeness or sufficiency, in particular, to assess the information about functions, features and the limitations of future software (especially about the quality) in this input information and identify the facts of the lack or insufficiency of the relevant information.

2 Related Works

For the assessment of life cycle initial stages, the knowledge of specialists, who already have experience in evaluating the level of initial stages for different types of software, has a significant value. The information about requirements is conveniently displayed in the form of ontologies, which provide displaying the cause-effect relationships between requirements. Ontologies are used for the representation of known information, the acquisition, structuring of knowledge and the formation of new knowledge of the subject domain. The advantages of ontologies using are the systematic approach to the subject domain study, the possibility of a holistic presentation of the subject domain known information, the identification of knowledge gaps and duplications based on the visualization of missing logical connections. Another advantage of using ontologies is the ability of information analysis by intelligent agents (this is very relevant in the current transition to the semantic web, when resources should be clear not only for the person but also for the agents) [7].

During operation, the intelligent agent uses the external information (environment's information), analyzes it, compares with internal information (already known information) and decides on further action on the basis of this analysis results [8].

A series of studies have been devoted to solving the problem of development of the ontologies and ontology-based intelligent agents for analysis and processing of the requirements of the medical software. Thus, in [9] there is the ontological approach to automated validation and measurement of requirements of the software system for the manufacturing the medical drugs, which is used to detect inconsistencies and drawbacks of software requirements. The authors [10] presented the ontology-based knowledge methodology, which is used to represent the requirements for a software system of visualization of the patient's clinical information. In [11] the ontologies are used for modelling the requirements for electronic health records (EHR), which not only allow the code reuse and enable its later extension and customization, but also transform the ontological models into deployment-ready code. The authors of [12] use the ontological agent-oriented models for the formalization of the initial requirements of Ambient Assisted Living applications (for patients with Parkinson disease) with the purpose of costs reducing. In [13] there is the agent-oriented paradigm, according to which there are the task-based support architecture and ontology-driven design for decision support systems on the example of clinical decision support systems in an emergency department, which allows the converting the functional requirements into the architectural components.

But the developed ontology-based intelligent agents don't solve the task of research and improvement of the characteristics of the input information for the specifications of requirements for medical software, and do not provide the quantitative assessment of the level of elaboration of initial stages of the life cycle of medical software on the basis of the analysis of specifications. The actuality of the task of evaluation of the software life cycle initial stages on the basis of specification analysis necessitates *the development of OBIA for improving the input information for the formation of specifications of requirements for medical software*.

3 Process of Improving the Input Information for Medical Software Requirements Specifications using Ontology-Based Intelligent Agent

Nowadays, the OBIA for assessing and improving the input information for the formation of specification of requirements for medical software performs only the analysis and improving the input information that relates to the evaluation of the quality characteristics and of the quality of developed medical software (analyzes the presence of measures of quality, and the ability to calculate quality subcharacteristics and characteristics of medical software - based on the standards of ISO 25010 [14], ISO 25023 [15]). Therefore, the intelligent agent uses base ontology of the subject domain "Software Engineering" (part "Software quality") as already known for it fact. The components of this base ontology were developed in [7]. IA compares the information from real M-SRS (real ontology) with known base ontology. On the basis of this comparison OBIA evaluates the information in real M-SRS, concludes the sufficiency of the information in the M-SRS and input information, provides the numerical evaluations of sufficiency of information in the specification and input information for determining the developed medical software quality, and provides recommendations for improving the input information for the formation of M-SRS (offers the addition of the business requirements, that regulate the measures, subcharacteristics and characteristics of quality, with indicating the missing measures).

The process of improving the input information (relates to the software quality) for the formation of M-SRS using the OBIA is presented on Fig. 1.

Method of activity of ontology-based intelligent agent for evaluating the initial stages of the software life cycle was developed in [16]. In accordance with this method, OBIA was currently realized for evaluating and improving the input information for the specification of requirements for medical software.

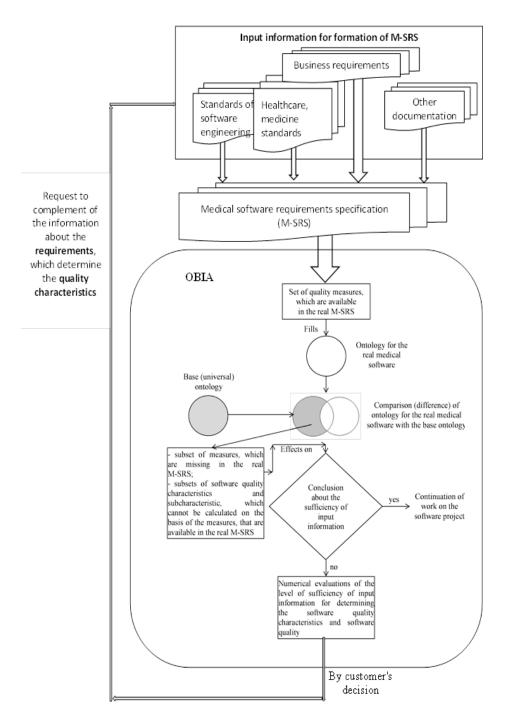


Fig. 1. The process of improving the input information (relates to the software quality) for the formation of M-SRS using OBIA

4 Improving the Input Information for Medical Software Requirements Specifications using Ontology-Based Intelligent Agent

For the experiment, the developed OBIA used the specification of requirements for the real medical software of the information and analytical system for the accounting of therapeutic and diagnostic activities provided to the wounded during transportation, which was developed by one of the software companies in Khmelnitsky. For evaluating the information on the availability of quality measures in this M-SRS, the developed intelligent agent has created real ontology of the subject domain "Software Engineering" (part "Software Quality") according to the specification of requirements for real medical software of the information and analytical system for accounting of therapeutic and diagnostic activities provided to the wounded during transportation. After that the OBIA compared real and base ontologies of the subject domain "Software Engineering" (part "Software Quality"), which resulted in the formation of the set of missing quality measures in this M-SRS: Number of Functions, Number of Data Items, Number of Tasks, Number of Evaluations, Number of Failures, Number of IO Related Errors, Mean Amount of Throughput, Number of Tutorials, Number of IO Data Items, Completeness of User Documentation and/or Help Facility, Number of Screens or Forms, Number of Interface Elements, Number of User Errors or Changes, Number of Interface Graphical Elements, Degree of Ergonomic Attractiveness, Number of Faults, Product Size, Number of Interface Protocols, Number of Access Types, Number of Controllability Requirements, Number of Modules, Number of Variables, Number of Checkpoints, Number of Installation Steps, Ease of Installation. Consequently, since the set of missing measures is not empty, the developed intelligent agent concludes that the information in the input information and in the specification of requirements for real medical software of the information and analytical system for accounting of therapeutic and diagnostic activities provided to the wounded during transportation is insufficient.

The developed OBIA conducted analysis of the impact of each element of the missing measures set on the subcharacteristics and the characteristics of the software quality on the basis of the components of base ontology of the subject domain "Software Engineering" (part "Software Quality"). This analysis provides the calculation of numbers of missing measures for each software quality subcharacteristics. In addition, on the basis of this analysis, the developed OBIA provides the conclusion based on the available measures in M-SRS for real medical software of the information and analytical system for accounting of therapeutic and diagnostic activities provided to the wounded during transportation, it is impossible to calculate 24 from 31 quality subcharacteristics (Functional Completeness, Functional Correctness, Functional Appropriateness, Time Behaviour, Resource Utilization, Capacity, Appropriateness Recognisability, Learnability, Operability, User Error Protection, User Interface Aesthethics, Maturity, Fault Tolerance, CoExistence, Interoperability, Confidentiality, Integrity, Modularity, Analysability, Modifability, Testability, Adaptability, Installability, Replaceability) and all 8 quality characteristics

tics (Functional Suitability, Performance Efficiency, Usability, Reliability, Compatibility, Security, Maintainability, Portability).

After this, the developed OBIA calculated the evaluations of the level of sufficiency of input information and information in M-SRS for determining the quality characteristics by the formula:

$$D_{j} = (k_{j} - \Sigma(qm_{i}/qn_{i}))/k_{j}, \qquad (1)$$

where k_j – quantity of subcharacteristics of j-th software quality characteristic (j=1..8, since there are 8 software quality characteristics in ISO 25010 [14]), i=1..k_j, qm_i – quantity of missing in real M-SRS measures for i-th subcharacteristic of j-th software quality characteristic, qn_i – quantity of necessary measures for i-th subcharacteristic of j-th software quality characteristic (these quantities are determined by the components of base ontology of the subject domain "Software Engineering" (part "Software Quality") for each software quality characteristic).

Thus, the agent provided the following evaluations of the level of sufficiency of input information and information in M-SRS for determining the quality characteristics of real medical software of the information and analytical system for accounting of therapeutic and diagnostic activities provided to the wounded during transportation:

$$\begin{split} D_{Functional_Suitability} &= (3 - (1/4 + 1/5 + 1/6))/3 = 0,79; \\ D_{Performance_Efficiency} &= (3 - (3/7 + 3/14 + 2/5))/3 = 0,65; \\ D_{Usability} &= (6 - (3/6 + 3/8 + 5/13 + 1/11 + 3/6 + 0/5))/6 = 0,69; \\ D_{Reliability} &= (4 - (3/14 + 0/4 + 2/5 + 0/7))/4 = 0,85; \\ D_{Compatibility} &= (2 - (3/4 + 1/5))/2 = 0,68; \\ D_{Security} &= (5 - (3/10 + 3/8 + 0/2 + 0/2 + 0/1))/5 = 0,87; \\ D_{Maintainability} &= (5 - (4/7 + 0/6 + 2/6 + 1/8 + 1/6))/5 = 0,76; \\ D_{Porrability} &= (3 - (3/11 + 3/4 + 2/3))/3 = 0,44 \end{split}$$

The developed OBIA also provides the evaluation of the level of sufficiency of input information and information in M-SRS for determining the software quality by the formula:

$$D = (k - \Sigma(qmc_j/qnc_j))/k, \qquad (2)$$

where k - quantity of the software quality characteristics (k=8, because there are 8 software quality characteristics in ISO 25010 [13]), j=1..k, qmc_j – quantity of missing in real M-SRS measures for j-th software quality characteristic, qnc_j – quantity of necessary measures for j-th software quality characteristic (these quantities are determined by the components of base ontology of the subject domain "Software Engineering" (part "Software Quality") for each software quality characteristic).

The OBIA provided the evaluation of the level of sufficiency of input information and information in M-SRS for determining the quality of real medical software of the information and analytical system for accounting of therapeutic and diagnostic activities provided to the wounded during transportation:

D_{Quality}=(8-(3/15+8/26+15/49+5/30+4/9+6/23+8/33+8/18))/8=0,70

Consequently, the developed OBIA provides the following conclusion: "In the input information and in the analyzed specification of requirements for medical software of the information and analytical system for accounting of therapeutic and diagnostic activities provided to the wounded during transportation, the available measures are insufficient for determining all characteristics. The level of sufficiency of available information for determining the Functional Suitability is 79%. The level of sufficiency of available information for determining the Performance Efficiency is 65%. The level of sufficiency of available information for determining the Usability is 69%. The level of sufficiency of available information for determining the Reliability is 85%. The level of sufficiency of available information for determining the Compatibility is 68%. The level of sufficiency of available information for determining the Security is 87%. The level of sufficiency of available information for determining the Maintainability is 76%. The level of sufficiency of available information for determining the Portability is 44%. The level of sufficiency of available input information and information in M-SRS for determining the software quality is 70%. There is a need of addition of the input information (in particular, the business requirements) that regulates the quality measures, and the addition of this specification by the measures that are necessary for determining all quality characteristics".

For ensuring the sufficiency of input information and information in the specification of requirements for real medical software of the information and analytical system for accounting of therapeutic and diagnostic activities provided to the wounded during transportation, the addition of specification with the abovementioned missing measures is necessary. For this developers should complete the input information (in particular, business requirements) that regulates such quality measures. In addition to the list of missing measures, developed OBIA also provides visualization of gaps in knowledge about the software quality characteristics - on the basis of the relevant components of base ontology of subject domain "Software engineering" (part "Software quality"), where missing attributes are the strikethrough, and subcharacteristics, for determining of which the available measures are insufficient, are outlined. Fig. 2, 3 show the visualization of knowledge gaps for the quality characteristics Usability and Portability (for other characteristics, the OBIA provides similar visualization).

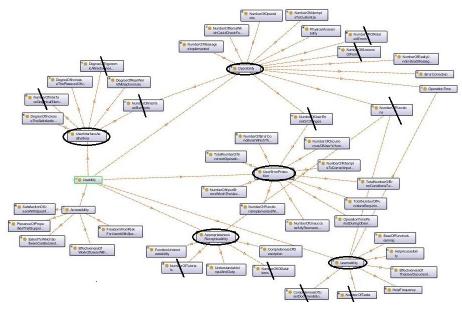


Fig. 2. The visualization of the knowledge gaps for Usability

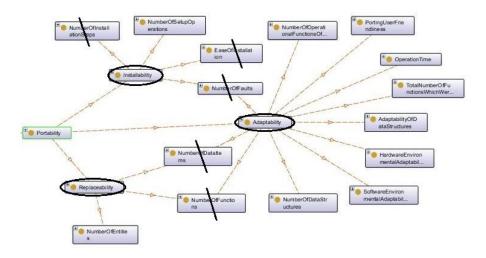


Fig. 3. The visualization of the knowledge gaps for Portability

The addition of input information and information in the specification of requirements for real medical software of the information and analytical system for accounting of therapeutic and diagnostic activities provided to the wounded during transportation was conducted. The following measures are added in this M-SRS: Number of Functions, Number of Data Items, Mean Amount of Throughput, Number of Interface Elements, Number of Tutorials, Number of Interface Graphical Elements,

Number of Failures, Number of Faults, Number of Interface Protocols, Number of Access Types, Number of Modules, Number of Installation Steps, Ease of Installation.

After that, the OBIA again calculated the number of missing attributes for the software quality subcharacteristics (after addition), and also formed the conclusion that on the basis of available after addition measures in M-SRS for real medical software of the information and analytical system for accounting of therapeutic and diagnostic activities provided to the wounded during transportation, it is still impossible to calculate 12 from 31 quality subcharacteristics (Time Behaviour, Resource Utilization, Appropriateness Recognisability, Learnability, Operability, User Error Protection, User Interface Aesthethics, Maturity, Confidentiality, Integrity, Modularity, Testability) and 5 quality characteristics (Performance Efficiency, Usability, Reliability, Security, Maintainability).

The developed OBIA provided the following evaluations of the level of sufficiency of input information and information in M-SRS (after addition) for determining the quality characteristics of real medical software of the information and analytical system for the accounting of therapeutic and diagnostic activities provided to the wounded during transportation:

 $D_{\text{Functional}_\text{Suitability}(add)} = (3 - (0/4 + 0/5 + 0/6))/3 = 1,00;$

D_{Performance_Efficiency (add)}=(3-(2/7+2/14+0/5))/3=0,86;

 $D_{\text{Usability (add)}} = (6 - (1/6 + 2/8 + 3/13 + 1/11 + 1/6 + 0/5))/6 = 0,85;$

 $D_{\text{Reliability (add)}} = (4 - (1/14 + 0/4 + 0/5 + 0/7))/4 = 0.98;$

 $D_{\text{Compatibility (add)}} = (2 - (0/4 + 0/5))/2 = 1,00;$

 $D_{\text{Security (add)}} = (5 - (1/10 + 1/8 + 0/2 + 0/2 + 0/1))/5 = 0.96;$

 $D_{Maintainability (add)} = (5 - (1/7 + 0/6 + 0/6 + 0/8 + 1/6))/5 = 0.94;$

 $D_{Porrability (add)} = (3 - (0/11 + 0/4 + 0/3))/3 = 1,00$

The OBIA also provided the evaluation of the level of sufficiency of input information and information in M-SRS (after addition) for determining the quality of real medical software of the information and analytical system for accounting of therapeutic and diagnostic activities provided to the wounded during transportation:

D_{Quality (add)}=(8-(0/15+4/26+8/49+1/30+0/9+2/23+2/33+0/18))/8=0,94

So, the developed OBIA provides the following conclusion: "In the input information and in the analyzed specification of requirements for medical software of the information and analytical system for accounting of therapeutic and diagnostic activities provided to the wounded during transportation, available measures are still insufficient for determining 5 quality characteristics. The level of sufficiency of available after addition of information for determining the Functional Suitability is 100%. The level of sufficiency of available after addition of sufficiency of available after addition for determining the Performance Efficiency is 86%. The level of sufficiency of available

after addition of information for determining the Usability is 85%. The level of sufficiency of available after addition of information for determining the Reliability is 98%. The level of sufficiency of available after addition of information for determining the Compatibility is 100%. The level of sufficiency of available after addition of information for determining the Security is 96%. The level of sufficiency of available after addition of information for determining the Security is 96%. The level of sufficiency of available after addition of information for determining the Security is 96%. The level of sufficiency of available after addition of information for determining the Maintainability is 94%. The level of sufficiency of available after addition of information for determining the Portability is 100%. The level of sufficiency of available after addition of input information and M-SRS information for determining the software quality is 94%. There is a need of addition of the input information (in particular, the business requirements) that regulates the quality measures, and the addition of this specification by the measures that are necessary for determining the remaining quality characteristics".

The customer was satisfied with such level of sufficiency of input information and information in M-SRS, so the further addition of the input information and the M-SRS has not occurred.

A diagram, which shows the level of sufficiency of input information and information in M-SRS for determining the quality characteristics and quality of real medical software of the information and analytical system for accounting of therapeutic and diagnostic activities provided to the wounded during transportation, before and after the addition is presented on Fig. 4.

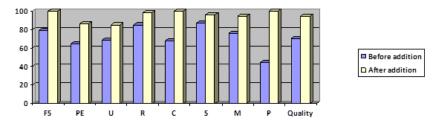


Fig. 4. Diagram of the improving the level of sufficiency of input information and information in M-SRS for determining the quality characteristics and quality of real medical software of the information and analytical system for accounting of therapeutic and diagnostic activities provided to the wounded during transportation

Improving the level of sufficiency of input information and information in M-SRS for determining the quality characteristics of real medical software of the information and analytical system for accounting of therapeutic and diagnostic activities provided to the wounded during transportation is from 9% (for Security) to 56% (for Portability). Improving the level of sufficiency of input information and information in M-SRS for determining the quality of this real medical software is 24%.

Thus, the developed OBIA provided the improving the input information for specification of requirements for medical software, namely, this OBIA provided the improving of its level of sufficiency for determining the software quality by 24%.

5 Conclusions

Today, in Ukraine, the problem of informatization of the healthcare industry is acute. One way of solving this problem is the development of medical software, successful implementation of which is critical for improving the efficiency of this industry. The main factor for successful implementation and operation of medical software is its quality. A significant number of errors are introduced in medical software at the requirements formation stage as a result of information losses due to incompleteness and difference of understanding of the information context and customers' needs.

The main sources of information during the formation of requirements for medical software are business requirements of a customer, standards of software engineering domain, standards of healthcare and medicine domain, descriptions of the software development and implementation process, etc. On the basis of the above input information, the software requirements specification is created. Therefore, for ensuring the quality of medical software, it is necessary to research and improve the characteristics of input information with the purpose of the identification and resolving the problems and disadvantages at the software life cycle initial stages.

The conducted analysis of the known OBIA showed that nowadays the task of research and improving the characteristics of the input information for the formation of specifications of requirements for medical software was not solved by the OBIAs. The known OBIAs do not provide the quantitative assessment of the level of elaboration of the medical software life cycle initial stages on the basis of analysis of specifications.

In this paper the scheme of the process of improving the input information (relates to the software quality) for the formation of M-SRS using the OBIA is developed. The OBIA is realized, which operates on the basis of the proposed scheme, evaluates and improves of the input information for the formation of the specification requirements for medical software, namely: concludes about the information sufficiency or insufficiency; provides the evaluations of the level of information sufficiency for determining each quality characteristic and quality in general; provides the list of measures, which should be added in the input information and in M-SRS with the purpose of increasing of sufficiency of its information; provides the visualization of knowledge gaps about all software quality characteristics.

For the experiment, the developed OBIA used the specification of requirements for real medical software of the information and analytical system for accounting of therapeutic and diagnostic activities provided to the wounded during transportation, which was developed by one of the software companies in Khmelnitsky. During the experiments, the OBIA concluded that the initial input information and information in this M-SRS were insufficient for determining the quality, the overall level of sufficiency of information for determining the quality was 70%, therefore it was recommended to add this specification and its input information with the necessary measures for calculation of the software quality characteristics (with the missing measures list and the visualization). It was decided to add the input information for formation of this specification of requirements for real medical software, namely, provide the improving of its level of sufficiency for determining the quality by 24%.

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