Maturity assessment of software-driven medical technologies: a quantitative score derived from a quality standard for the research phase

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Abstract— **Quantitatively assessing the level of readiness of medical technology improves its chance of successfully transfer from research to industry but remains a challenge. As many innovative medical devices are associated with or incorporate software, this article presents a methodology for evaluating the software maturity of a "Software-driven Medical Technology" (SdMT) during the research phase. A technological maturity model is developed by methodologically extracting relevant terms from the ISO/IEC 62304 standard, the main industry standard for medical device software, and results in a list of required software engineering artifacts. This list and the relative weight of the artifacts are used to establish a software maturity score for SdMT and the corresponding assessment questionnaire. The consistency of the model is demonstrated by analyzing the obtained score system relatively with the standard. The maturity score of a SdMT can be assessed during the research phase and depends on the number and importance of the artifacts already present at the time of evaluation.**

Clinical relevance— **The proposed quantitative maturity score can help the medical technology innovation actors (clinicians, researchers and industrials) to better identify, improve and fasten the readiness of technology for clinical investigation and technology transfer.**

I. INTRODUCTION

Obstacles to the emergence of new medical devices from research are numerous [1], [2], [3]. One of the main difficulties of technology transfer is the time and effort required to achieve compliance with regulations.

Many research projects have been conducted to better consider the regulatory burden and to make the technology more easily actionable during the industrialization phase. For instance, the author of [4] proposes to use industrial techniques such as robust design directly when building the proof of concept prototype during the research phase. As for the imbalance between functionality and compliance, the authors of [5] proposes to enter the quality-driven process as early as possible, using an integrated process. Imposing industrial technique or certification process during the research phase could, however, seriously impair the innovation process during which flexibility and interaction with clinicians is mandatory to yield to the best possible and useful results.

As many medical devices are associated with or incorporate software, our study focuses on assessing the maturity of what we call "Software-driven Medical Technologies" (SdMT). A SdMT is a health technology with the potential to become a medical device, but is still in the research stage. In a typical scenario, the industrialization phase starts after the technology transfer, where the SdMT will be progressively transformed under regulatory constraints into a Software-driven Medical Device (SdMD), as defined in [6], that can be commercialized. The ISO/IEC 62304 standard (Medical device software - Software life cycle process) [7] is the main standard that applies to medical device software in worldwide regulations and therefore directly impacts the technology transfer. Quantitatively assessing the level of readiness of SdMT to enter a regulatory or industrialization process is crucial as it helps to estimate and organize the effort required during the technology transfer. Such an objective estimation will increase the probability of success of innovative technology to become a new medical device.

Evaluating the software maturity of a SdMT during the research phase remains a challenge as its evolution is iterative by nature, trial and errors usually driving the process, and complete software specification only occurring at a later stage. A classical way to consider the maturity of technology is to use the Technology Readiness Level (TRL) [8]. Unfortunately, TRL can be subject to interpretation, and there is no single definition nor method to quantitatively assess the TRL of a given SdMT. Some rationalization efforts have been made to adapt the TRL scale in specific fields to obtain a more practical and quantitative assessment (e.g., for the chemical industry [9]), but to our knowledge no specific work has been done in the field of medical devices.

In this work, we propose a method to compute a quantitative maturity score by considering the different software products or by-products (e.g., source code, test, documentation, requirement specification, versioning) created during the development of a SdMT. A SdMT is viewed as a composition of Software Engineering Artifacts (SEAs). These SEAs are evaluated with respect to the one mentioned in the standard and required by the regulations. This paper presents our methodology for establishing a technology maturity model based on these SEAs and the resulting quantitative assessment questionnaire.

II. MATERIALS AND METHODS

Our maturity model is based on two assumptions: **(1)** The ISO/IEC 62304 standard specifies the quality guidelines and process required to comply with regulatory requirements,

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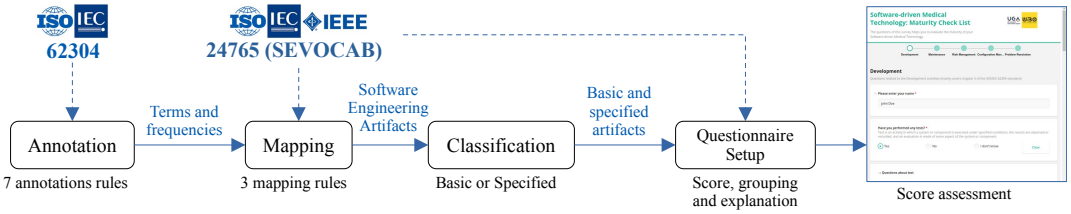

Fig. 1: From ISO/IEC 62304 standard to the maturity score assessment in four stages.

and therefore mention the related SEAs, sometimes using specialized terms; **(2)** the presence of these SEAs in SdMT can be used to quantify a technical degree of maturity with respect to regulatory requirements, independently of the quality guidelines and processes needed to meet all regulatory constraints. Our methodology follows four stages in order to create the maturity model of a SdMT: extraction of the terms describing SEAs from the ISO/IEC 62304 standard, mapping of the extracted terms acknowledged SEAs, classification of SEAs, and assessment questionnaire construction, see Fig. 1.

A. Annotation of the ISO/IEC 62304 standard

The ISO/IEC 62304 standard is the main standard addressing medical device software development. The entire 92 compliance requirements are stated in 5097 words, and describe five processes from sections 5 to 9 of the document: development, problem resolution, configuration management, risk management and maintenance. The requirements described in the standard contains references to SEAs, although sometimes using specialized or specific terms.

The first stage of our method consists of manually annotating the text of the standard in order to extract all the terms related to software engineering in the requirement statements. Seven simple and explicit rules are applied during the annotation process to ensure that the annotation is accurate and reproducible. The main rules are consider terms in their singular form, annotate distinct terms when different meanings are implied, and ignore terms that do not represent nor are linked to SEAs (e.g., actors and stakeholders). This stage results in a list of all the software engineering terms used in the standard, the requirements in which they are cited and the total number of citations of each term.

B. Mapping annotated terms to SEAs

The Systems and software Engineering VOCABulary (SEVOCAB), a joint project of IEEE and ISO/IEC, is a widely accepted lexicon in the field of software engineering available online [10]. It contains 5008 terms from 188 different ISO and IEEE international sources. It was used as a reference for the terms used in the software engineering field.

This second step of our method consists of searching for a correspondence between the annotated terms and the software engineering terms defined in the SEVOCAB. From the manually annotated terms in the standard, three matching rules are used to define either (1) a direct match (when an annotated term is found as is in SEVOCAB), (2) a combination match (when an annotated term is a combination of two or more SEVOCAB terms), or (3) a manual match (when an annotated term is syntactically different but has the same meaning as a SEVOCAB term). This step results in a list of SEAs cited in the ISO/IEC 62304 standard but isolated from the requirements and quality control context and described by their SEVOCAB definitions. This ensures that the SEAs used in our maturity model are defined independently of a quality standard source and are directly linked to an acknowledged source in the software engineering field.

C. Refining model using SEAs classification

The third step in our method is to separate the basic SEAs from the specified SEAs. Basic SEAs are tangible by-products of software development, typically found in the first phase of a SdMT, while specified SEAs are typically documents that specify the requirements, design, behavior, or other characteristics of the system under development. SEAs are classified as specified if and only if their names include suffixes such as “Documentation”, “Evaluation”, “Analysis” or “Management”. All other SEAs are classified as basic. This stage results in a refined maturity model composed of two lists of SEAs (basic and specified). This classified the SEAs according to the level of effort required to achieve them.

D. Setting up the score and maturity assessment questionnaire

The last stage of our method involves setting up the maturity score and maturity assessment questionnaire.

The score is based on *(a)* the assessment of the presence of the basic and specified SEAs in SdMT and *(b)* on their importance in the standard as measured by the number of citations of the corresponding annotated term. The maturity score can therefore be expressed as:

$$Score = \frac{1}{N}\left(\sum_{i=1}^{|\mathscr{B}|} n_{\mathscr{B}_i}[\mathscr{B}_i] + \sum_{i=1}^{|\mathscr{S}|} n_{\mathscr{S}_i}[\mathscr{S}_i]\right) \tag{1}$$

$$[\mathscr{B}_i] = \begin{cases} 1 & \text{if } \mathscr{B}_i \text{ is present in the SdMT} \\ 0 & \text{if } \mathscr{B}_i \text{ is not present in the SdMT} \end{cases} \tag{2}$$

$$[\mathscr{S}_i] = \begin{cases} 1 & \text{if } \mathscr{S}_i \text{ is present in the SdMT} \\ 0 & \text{if } \mathscr{S}_i \text{ is not present in the SdMT} \end{cases} \tag{3}$$

where $n_{\mathscr{B}_i}$, respectively $n_{\mathscr{S}_i}$, denotes the number of citations of $\mathscr{B}_i$, the i^{th} basic SEA, respectively $\mathscr{S}_i$, the i^{th} specified SEA; $[\mathscr{B}_i]$, respectively $[\mathscr{S}_i]$, takes the value 1 if $\mathscr{B}_i$, respectively $\mathscr{S}_i$, is a SEA present in the studied SdMT, or 0 if it is not present; N is the total number of citations

($N = \sum n_{\mathscr{B}_i} + \sum n_{\mathscr{S}_i}$); and $|\mathscr{B}|$, respectively $|\mathscr{S}|$, the total number of basic SEAs, respectively specified SEAs.

The contribution to the maturity score of basic SEA $\mathscr{B}_i$, respectively specified SEA $\mathscr{S}_i$, can be determined by $\frac{n_{\mathscr{B}_i}}{N}$, respectively $\frac{n_{\mathscr{S}_i}}{N}$.

The maturity assessment questionnaire is constituted by dichotomous questions that evaluate the presence of each SEA in the SdMT. The questionnaire is organized according to the five main processes presented in the ISO/IEC 62304 standard. Additionally, the questionnaire shows the definition of each SEA as described by the SEVOCAB. SEAs are grouped together depending on their relative dependence (e.g., the SEA "Integration Test" is grouped within the SEA "Test"). This allows simplifying the questionnaire by presenting sub-questions if and only if the answer to the main question is positive (e.g., the presence of the "Integration Test" SEA does not need to be assessed if the more general "Test" SEA is not present).

III. RESULTS

Annotation, mapping and classification

A total of 166 different terms were annotated in the text of ISO/IEC 62304 standard. The total number of citations is 538, including 132 citations in the requirement titles and 406 citations in the requirement descriptions. The mapping step resulted in 157 SEAs, and the classification step differentiated them into 38 basic SEAs and 119 specified SEAs, where 36 (22%) were obtained from the annotated terms of direct match with SEVOCAB, 95 (57%) by combination match, and 35 (21%) by manual match.

Fig. 2 shows the twenty most cited SEAs. Among which there are 9 basic SEAs, with a number of citations of 24 for the most cited basic SEA "Software Item", and 11 specified SEAs, with a number of citations of 29 for the most cited specified SEA "Software Requirement". All the most cited SEAs were obtained by direct match.

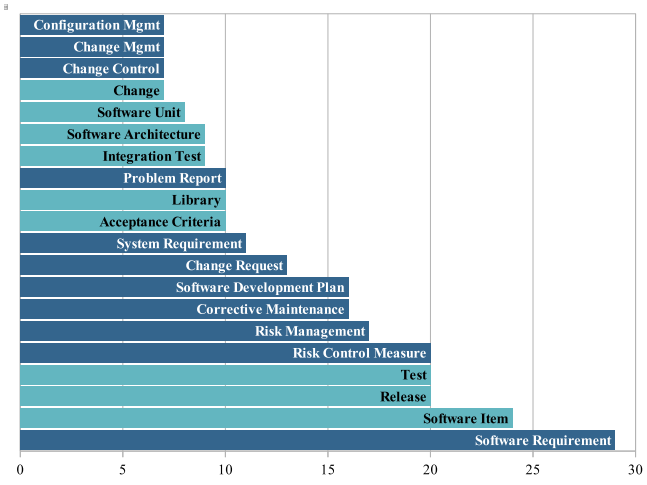

Fig. 2: The twenty most cited basic (light blue) and specified (dark blue) SEAs summing up to a total of 270 citations. The number of citations is shown on the x-axis.

Fig. 3 shows the distribution of basic and specified artifacts among the five activities described in the ISO/IEC 62304 standard. The software development activity is the longest chapter of the standard and contains the highest number of citations with 326 citations in total, representing 61% of the total number of citations. This activity also contains the highest proportion of basic SEAs among all activities, with 115 citations of basic SEAs, representing 66% of all basic SEA citations.

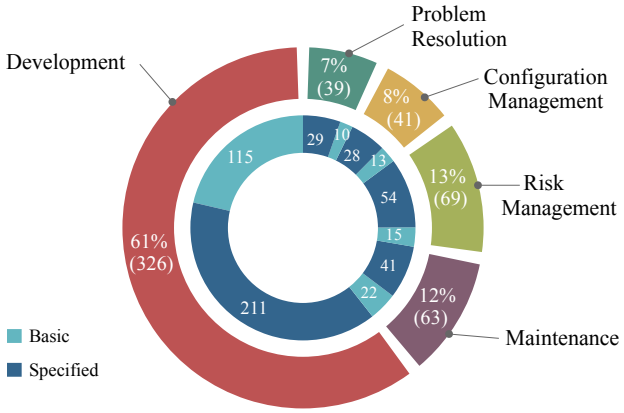

Fig. 3: Number and percentage of citations (outer pie) and distribution between basic SEAs (light blue) and specified SEAs (dark blue) for each main activity of the standard.

Questionnaire setup

Considering the score as stated in equation (1), the annotated step resulted in $N = 538$, $|\mathscr{B}| = 38$, $|\mathscr{S}| = 119$. When all the $|\mathscr{B}| + |\mathscr{S}| = 157$ SEAs are present in the SdMT, the maturity score is 100%. The contribution of each SEA to the score can be individually calculated. The number of citations of the most cited specified SEA, "Software Requirement", is 29. Therefore, if the "Software Requirement" SEA is present in the SdMT, then the maturity score is increased by $\frac{29}{538} = 5.4\%$.

The maturity assessment questionnaire can be derived directly from the list of SEAs by building dichotomous questions to evaluate the value of $[\mathscr{B}_i]$ and $[\mathscr{S}_i]$, i.e., assess the presence of a given SEA in the SdMT. For example, the most cited basic SEA "Software Item" is associated with the dichotomous question "Have you identified any software items?".

Fig. 4 provides a screenshot of the first page of the resulting questionnaire. The questions are grouped by the five main activities outlined in the ISO 62304 standard and then by their relative dependence as explained in the previous section. For instance, if the user answer "Yes" to the question "Have you performed any tests?", the panel "Questions about test" that groups all the questions about test SEAs, is made visible (see Fig. 4).

IV. DISCUSSION AND CONCLUSION

The proposed methodology extracts all the SEAs referenced in the ISO/IEC 62304 standard independently of their usage in the described quality control process.

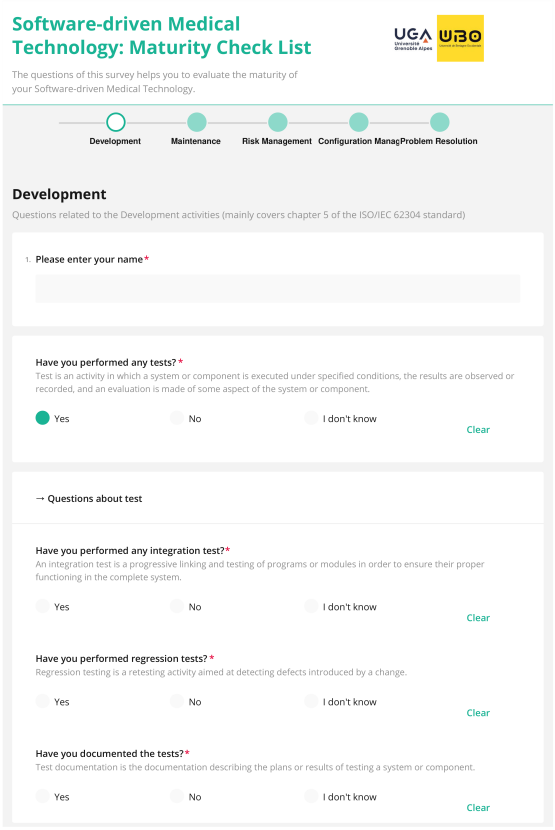

Fig. 4: Resulting maturity assessment questionnaire (extract).

The location of the citations and the proportions between basic and specified SEAs, as shown in Fig. 3, appear to be consistent with the nature of the standard: *(a)* there are more specified than basic SEAs, which reflect the objective of the standard; *(b)* the development section contains the highest proportion of basic SEAs while the lowest is in the risk management section, which reflects the nature of the described activities. This is consistent with our first assumptions.

79% of the mapping was found either directly (as for all the most cited SEAs) or as a combination of SEVOCAB terms. This shows that both the extraction from the standards and the mapping to SEVOCAB are sensible and consistent with our assumptions. Using terms and definitions from the SEVOCAB allows the SdMT team to better understand and identify the SEAs mentioned in the standard, even if the team members are not familiar with quality processes and regulatory requirements.

As SEAs are classified between basic and specified, the maturity model can be used even during the early stage of the SdMT developments, where usually almost all SEAs are basic. The nine most cited artifacts amount for $\frac{99}{538} = 18.4\%$ of the score and can be defined as a first maturity level target. Putting aside "Risk Control Measure" and "Risk Management", the eighteen most cited SEAs amount for $\frac{233}{538} = 43.3\%$ of the total possible score (Fig. 2), which seems a reasonable objective even in the initial phase of a research project, when the intended medical purpose is not fully established. Using the number of citations in the score is a practical way of establishing the relative importance of SEAs. Although it seems logical that a higher number of citations means a higher relevance, the content validity of our score still needs to be verified.

Other future works include the use of our maturity model to complement guidelines such as the one proposed in [11]. The presence/absence of SEAs, their relative dependence and contributions to the score, could be used to define personalized maturity stages throughout the life of SdMTs.

It is important to note that a maximum score does not necessarily guarantee clinical safety or direct commercialization of medical technology. These decisions have yet to be made by regulatory authorities and healthcare professionals. Nevertheless, the proposed maturity score is a first step to quantitatively estimate the readiness level of a SdMT to enter technology transfer or clinical investigation. It can be used to provide a quicker access for the patients to new and innovative treatments and diagnostic tools.

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