Transdisciplinarity and the Future of Engineering B.R. Moser et al. (Eds.) © 2022 The authors and IOS Press. This article is published online with Open Access by IOS Press and distributed under the terms of the Creative Commons Attribution Non-Commercial License 4.0 (CC BY-NC 4.0). doi:10.3233/ATDE220661

# Conceptual Approach for a Digital Twin of Medical Devices

Roberto RIASCOS<sup>ab1</sup>, Egon OSTROSI<sup>b</sup>, Jean-Claude SAGOT<sup>b</sup> and Josip STJEPANDIĆ<sup>c</sup> <sup>a</sup>Roche Diabetes Care GmbH, Germany <sup>b</sup>ERCOS/ELLIADD EA4661, Univ. Bourgogne Franche-Comté, UTBM, F-90010 Belfort, France <sup>c</sup>PROSTEP AG, Germany

Abstract. Over the last few years, a concept called Digital Twin has emerged continuously as a comprehensive approach in industrial domains. The concept comprises a description of strong coherence between physical products, processes, or services "as delivered" and their virtual surrogates. Internet-of-Things technology has drastically lowered the costs of Digital Twin Computing. It builds the foundation for connected products and services. Three main characteristics of Digital Twin have been identified: representation of a physical system, bidirectional data exchange, and connectiveness along the entire lifecycle. We have explored this concept in non-technical disciplines and have found several similar approaches for interaction between the real world and its digital surrogates: Digital Twins in medicine. Digital twin technology has the potential to transform healthcare in a variety of ways improving the diagnosis and treatment of patients, streamlining preventive care and facilitating new approaches for hospital planning.

Keywords. Digital Twin, Medical Device, Modular Design, Product Lifecycle Management, Transdisciplinary Engineering

## Introduction

The concept of the Digital Twin (DT) consists of generation, maintainance and use of the virtual surrogate of an object or system during its entire lifecycle. The aim of this approach is to achieve a high-fidelity product/system definition, verification, and validation including the modes of failure. By gathering and processing real-time data, the physical system can be monitored with its DT, while (potential) problems can be detected early, communicated with the physical system, and dealt with accordingly [1].

The concept was introduced in the manufacturing realm, but is increasingly used in other domains. This concept requires a transdisciplinary approach for its creation, implementation, and use. Knowledge of of several disciplines are needed such as manufacturing, business disciplines of operations and quality, human behaviour, and technical knowledge are required. Collaboration between experts from these different disciplines is a prerequisite to fully exploit the DT concept.

In this paper, we will briefly describe how to derive the Digital Twin concept of medical devices based on experience from various domains, primarily manufacturing. In

<sup>&</sup>lt;sup>1</sup> Corresponding Author, Mail: roberto.riascos@roche.com.

addition, we will present the way how to exploit the outcome of research and application in another domains to benefit the Digital Twin of medical devices. The Digital Twins will be compared in a transdisciplinary view.

The outline of the paper is as follows. In section 1, the concept of DT with its taxonomy and the transdisciplinary approach is introduced. In section 2, the recommendations for Digital Twin of Medical Device are described. In section 3, we will discuss the challenges that still exist in the manufacturing and construction domain as well as for the concept to mature in the medical domain. The concrete use case Battery Digital Twin is described in section 4. The paper ends with a discussion and outlook.

#### 1. Basic characteristics of a Digital Twin

Digital Twin was meant to improve industry competitiveness, especially in manufacturing, to meet challenges caused by volatile demand, lower batch size and high cost pressure. A DT can be broken down like an assembly. A discrete DT is a single entity that provides value without the need to be further broken down. For example, a module of a car (e.g., the engine) can be considered at this entity level. The discrete DT can be assembled into a composite Digital Twin that represents an entity that may comprise multiple individual components or parts. For example, a car is a composite entity, whose DT consists of the composed DT of the modules within the car. A fleet is a system, whose DT consists of several others composite Digital Twins [2]. It is worth noting that each variant can be understood as an instance of a DT.

The kernel of a DT consists of the simultaneous occurrence of the physical product and its digital surrogate, in particular in manufacturing. The surrogate model provides a virtual representation of the real system or object. Here, only those properties of the real system are mapped in the digital model that lead to an accurate virtual representation of system behaviour. With the digital model, it is possible to perform simulations and conduct analyses and evaluations that were previously done either by expert knowledge or mathematical calculations. However, since the digital model can be applied to integrate complex interdependencies, statistical distributions and scenarios into the investigations, new evaluation and analysis possibilities emerge. This occurs in particular when the DT interacts with the real system. As a result, analyses and evaluations become more reliable, faster, and the DT provides decision-making for complex planning and control problems [4].

The reason why DTs are becoming more and more attractive for industry is primarily caused by two characteristics: their ability to integrate large amounts of static, real-time, structured and unstructured data and to combine these data with advanced data processing methods such as artificial intelligence, machine learning or high-performance computing to provide simulation, control and self-improvement [5]. These capabilities are particularly important whereof the human well-being or health can be improved.

In research and practice, many types and expressions of Digital Twin can be found for a plethora of use cases along the product lifecycle within Product Lifecycle Management (PLM). Three definitions of Digital Twins can be identified: 1) the Digital Master, 2) the Digital Manufacturing Twin, and 3) the Digital Instance Twin. These definitions represent the phases design, manufacturing and exploitation, respectively [6]. Approaches to Digital Twin examples can be found in a vast array of domains. For all expressions of Digital Twin in different domains, an (almost) common taxonomy is necessary and useful.

## 1.1. A taxonomy for Digital Twin

For comparing and distinguishing specific types of Digital Twin, an appropriate taxonomy is necessary [7]. We have selected dimensions that may apply also to other domains than manufacturing. These dimensions are selected for comparison between different domains later in this paper (see Table 1).

Dimension	Characteristics			Exclusivity
Data link	One-directional		Bi-directional	Mutual
Purpose	Processing	Transfer	Repository	Not
Accuracy	Identical		Partial	Mutual
Synchronization	With		Without	Mutual
Data input	Raw data		Processed data	Not
Time of creation	Physical part first	Digital part first	Simultaneously	Mutual

 Table 1. Taxonomy of Digital Twin, derived from [7].

The dimension data link specifies how communication between the Digital Twin and its physical counterpart takes place, which can either be one-directional or bidirectional and is, therefore, mutually exclusive. The way of handling data by a Digital Twin has three, not mutually exclusive, characteristics: 1) processing data such as monitoring, analysis, forecasting, or optimization; 2) transfer data from one point (e. g., the physical part) to another one (e. g., a data warehouse); 3) data repository. Model accuracy concerns the accuracy of expression of the physical object in the digital representation: either by an identical accuracy or a partial accuracy, and is mutually exclusive as well [7].

The dimension synchronization consists of two characteristics: 1) active synchronization between the Digital Twin and the physical part by (real-time) data updates during its lifecycle or 2) without synchronization, and is mutually exclusive. The dimension data input differentiates between raw and processed data, which can be data received from sensors or databases, or pure or raw data gathered directly from sensors or other data collection devices. In addition, data might be used that are pre-processed (e. g., by analytic software) before it is transferred to the Digital Twin. Data input is not mutually exclusive [7].

The dimension time of creation distinguishes between three characteristics determining the chronological order in which the respective parts of a Digital Twin come into existence. Therefore, the dimension distinguishes whether the physical part or the digital part is developed first, or both parts are developed simultaneously. Most Digital Twins are designed after a physical system has been created [7]. In the wide area of healthcare, the medical device industry is a significant field for Digital Twin (Figure 1). In the medical device industry, the digital part must be provided to fully leverage the benefits of the Digital Twin. Based on Table 1, this Digital Twin preferrably uses a bidirectional data link for the raw data as the data input, that is synchronized with relative accuracy.



Figure 1. Application of Digital Twins in healthcare.

## 1.2. The need for a transdisciplinary approach

A transdisciplinary approach is essentially a process of knowledge exchange between different disciplines, needed to solve a complex, real-life problem, or a problem that has a large impact in society, which may include a large network of companies and their environment [8]. Preferably, these disciplines do not only comprise technical disciplines, but also disciplines from other science fields (e.g. medicine, economy, management). Moreover, stakeholders from practice need to be involved strongly, in particular if the risk for humans exists [9]. Similar to the general development of technical products, the trend at medical devices is towards personalized medicine with the Digital Twin as a powerful support [10].

For developing a Digital Twin, the intended application and use need to be considered as well as the potential impact of the Digital Twin on the processes and people in the organisation. For example, a Digital Twin of a component of a medical device has a significant downstream affect that must be considered: it has an impact on both the design and the production process, it has an impact to the users/patients using the device and the healthcare professionals supporting this use, and the knowledge needed to operate and use the Digital Twin must be kept current [11]. Moreover, the Digital Twin may impact the profitability and market opportunities of the belonging company e.g. by providing additional opportunities by exploiting the operational data [12]. Stakeholders from business, human resource management and finance need to be involved in adopting, designing and developing a Digital Twin. In addition, medical ethics and law might also play an important role e.g. the define state of urgency [13].

Implementation of a Digital Twin in real practice is not an easy task. Decisions for which approach to take need to be made by a team with stakeholders from different business departments, because the impact of a Digital Twin is often wide-spread [14]. In addition, the implementation process needs to be monitored by the same team regularly.

While the Digital Twin is in use, a regular team session is needed to evaluate the operation of the Digital Twin and its impact on the business [15]. A continuous improvement approach will be needed.

Like with all large high-impact changes in a business environment, different disciplines need to be involved to anticipate, monitor, and repair potentially harmful impact of the adoption, development, and use of a Digital Twin [16].

## 2. Recommendations for Medical Devices Digital Twin realisation

Based on the current research achievements, this section aims to provide the key ideas facilitated with the conception, deployment and use of a DT of an individual medical device, by looking at the perceived DT abilities and features from other domains, primarily manufacturing [17] and construction [18]. The generation of a DT should be a continuous, evolving process, depending on the implemented technologies based on characteristics shown in Table 1. Within the manufacturing industry, the DT is referred to as having all the "useful" information across the entire product lifecycle. This also applies to the building and infrastructure lifecycles, but at a much larger scale and inherently different dynamics. The affected phases and related domains are partitioned in Figure 2. The underlyining product structure is built in PLM system and should contain the requirements, the functional, the logical and the physical product structure. The DT basically belongs to the functional view but is strongly interconnected with the physical structure.

The progress in the implementation of a DT is expected to be gradual, but continuous over the product lifecycle, driven by the extension of the supply chain integration and the customers' feedback. The eventual merge between virtual models and sensing would converge on a common semantic web platform [18]. The adoption of methods and techniques of artificial intelligence (AI) represents the final step for the time being, which is expected to progress after sufficient training and careful verification of the AI behaviour are carried out under consideration of consequences on the patient's health. This represents the transition of certain decisions from human control and guidance to limited DT agency.



Figure 2. Conceptual framework for Digital Twin of medical device, derived from [17] and [18].

#### 2.1. Smart design

The large-scale development of medical devices relies on both mechanistic and datadriven techniques and requires the integration and ongoing update of multiple module and component models developed across many different laboratories. The intent of a DT with the full functionality described in Table 1, is to enable accurate sensing capabilities, as well as highly performant communication and interoperability [20]. In analogy to typical approaches for preventive maintenance of complex products, DTs of medical devices comprise the computational models of biological processes calibrated to individual patients using multiple heterogeneous data streams.

Digital Twins of a medical device should collect information on the condition of a patient, including his location. Besides checking compliance to safety rules (e.g. change of a bandage) it could also further detect eventual abnormal behaviours such as dizziness, fall, or even monitor his fatigue and attention between two inspections. Modularity is a key characteristic here to reduce the complexity and costs [21]. The modular architecture needs to be designed to make the process of model expansion and alteration not just feasible but quite straightforward [22].

The design framework should be able to provide a performant interoperability and be generally applicable to all model types. A problem that needs to be solved for the design of hybrid models that integrate different modeling frameworks is the transformation of data types between models. The utilization of powerful design templates can facilitate this process [23], in particular for cross-domain tasks. All modules either store data in a global model state, or forward data directly to one another. Finally, a good design should provide the architecture and means to collect and analyze data and make decisions.

#### 2.2. Smart monitoring

The first implementations of a DT were monitoring platforms which enable sensing of the physical, with some degree of reporting and analysis capabilities [18]. Conversely, the human body has numerous distinctive physiological signs that can be acquired and interpreted: from electrical signs to biochemical, human signs are removed and be utilized to more readily comprehend for the wellbeing status. Contemporary innovation and wearable situations arrange wearable health devices as per three perspectives: situation of utilization (home/far off or clinical climate); the status of interconnecting (disconnected or on the web); and the pretended sort of client (solid or patient). IoT-enabled devices facilitate remote monitoring in the healthcare including the "informative self-monitoring" of the patient, unleashing the potential for a timely care with an increased patient engagement and better interactions with physicians [12].

Thus, issues persist in terms of validating the data (correctness and completion), correctly interpreting it (applying semantics) and processing it in an effective manner to facilitate real-time responses. The application of automated health monitoring techniques can lie on the basis of artificial intelligent algorithms. This DT framework could get a good performance in monitoring the working status due to its self-learning ability [14].

Visualisation is an important mean in monitoring for devices under changing states and conditions [19], being at the core of team communication and decision-making, benefitting of up-to-date, real-time data feeds from multiple sources. Cross-checking and cross-referencing data from different models and periods, combined with an external data platform, would bring forth more valuable insights to the patient and care staff.

## 2.3. Smart control

Smart control can be realized in the different phases of the product lifecycle of a medical device. With DT now being part of the initial procurement and the design-manufacturing operation phases, the emphasis of the DT should be on detail design and manufacturing phases when the physical twin gets built which is well covered by PLM systems. While PLM processes are able to deeply facilitate engineering collaboration through the use of common practices, a PLM system is functionally limited when in the scope of IoT and dynamic auxilary data. A DT assumes a cohesive integration of models, sensors and services, enhanced by synchronicity [18]. Additionally, users from different social and educational backgrounds should be able to interface with the DT, which is set to vary according to specific sub-domains of healthcare over the lifecycle.

Such solutions are realized and matured by e.g. innovative medical devices in haemodialysis, where therapy control and responsibility is going to be delegated to and adopted (at least in part) by medical devices. Noninvasive sensors are increasingly capable to continuously assess and control physiological parameters of a patient. When applied as a closed loop and linked to the dialysis monitor, treatment conditions can be acutely modified and adapted depending on the patient's performance [13].

## 2.4. Smart scheduling

Shortcomings in a performant information integration can be observed on all levels. Semantic Digital Twin applications promise the ability to connect the various planning systems, as well as to link the heterogeneous datasets in order to provide an improved surgery planning. Artificial Intelligence may also bring added-value to human agents in such negotiation-intensive management approaches, like advising the professionals on optimised duration, sequencing etc [18].

Smart scheduling primarily uses advanced models and algorithms to extract information from the data collected by sensors. Data-driven techniques and advanced decision architecture can be used to perform smart scheduling. For example, distributed intelligent models using a hierarchical interactive architecture can be used for reliable real-time scheduling and execution. Operational behavior and processes can then be carried out automatically and effectively due to the established structures and services. With the help of data input mechanisms, the output resolutions are fed back to the participants in different ways [17].

## 2.5. Intelligent integration platform

There are advanced monitoring platforms with limited intelligence that take the first major step toward semantics, employing a common web language framework to represent the DT with all its integrated IoT devices to form a knowledge base. Focused intelligence is achieved by using embedded knowledge rules and separate AI-based algorithms to enable simulations and predictions [24]. Optimization would be a process largely performed by trained human actors. Actuation capabilities are limited to safety, security, and energy consumption, and provide detailed warnings and recommendations that require user validation and authorization for more complex situations. This places the DT in a complex socio-technical dilemma in which the DT must adapt and respond in real time to its users and to dynamic changes that occur on a daily basis [18].

## 3. Use case Battery Digital Twin

A portable medical device composed of several critical modules is developed in parallel with DTs of the modules to ensure product quality and user satisfaction while failure of any of them could lead to patient harm. In this case the device needs an appropriate power supply which is provided by an exchangable battery with capacity for 3 weeks. The output of the battery depends on the several parameters such as:

- Usage, how often the device is used with the corresponding usage profile and the functionalites triggered,
- Environmental, the battery output depends on the environment temperature and humidity
- System, the amount of energy consumed by the device's systems, some of which could be of high power consumption.

In order to ensure a usable device during the estipulated timeframe the R&D department invests heavily in battery tests, collecting data to design the device to meet a standard profile. In parallel these tests help the R&D department to find the batteries in the market that deliver the above metioned profile needs. The standard usage profile is clearly framed in the product's requirements and specifications.

Given the nature of the agile development of the product, performing extensive and long lasting battery tests for each product change was impracticable for the short release iterations of the product. To solve this, the department decided to implement a DT of the battery that will grow in parallel with the real product and which shall be able to faithfully represent the product in short cycled simulations to support an iterative release (marked with an arrow in Figure 2).

In this use case the R&D department partners with a supplier that has extensive experience in the matter of battery simulations and supports several industries in this field (Figure 3). Based on the requirements and specifications created, edit and controlled in the Application Lifecylce System (ALM) by the R&D department. User requirements are used to define several usage profiles; availability and costing requirements define batteries in the market to be considered to create the DT.

The supplier building the DT procures the short listed batteries and characterizes them using laboratory testing. The results are validated with the physical tests performed with the devices and baterries in several conditions. The results are fed into the DT of the battery. During the development process and any change in the design, an impact analysis will determine if the battery is impacted, in which case a DT simulation/update will be triggered. Based of the change the new usage profile shall be determined.

A DT based simulation is triggered using the new design parameters and the new usage profile. Results of the DT simulation may differ, these can validate the proposed changes or trigger further modifications. Another possible result is the usage of another battery brand to perform optimally with the new design. The documentation resulting from the simulation is referenced to the item in the PLM system that represents the battery. The documentation is referenced to the updated version of the battery prior to the official release of the item. The released item determines which batteries will be procured and built into the next physical version of the device. The new information is stored in the PLM system and made available through a dashboard. The dashboard information shows the relation between the latest simulation and the specified expectations of the battery. The DT simulation is updated if the requirements or specification are updated, or if a new battery is considered for characterization.

While this model is intended to support development, it shall be extended with internet of things capabilities to track real time battery usage to refine the DT model.



Figure 3. Use case Battery Digital Twin.

## 4. Conclusions and outlook

The main objective of a healthcare system is to ensure the patient's health and well-being by provision of an adequate therapy and care on a high level of quality and sustainability [25]. By using methods of system science and systems engineering, the implementation of engineering and IT solutions to support or replace singular human functions is a rapid emerging way for further progress. The new, often breakthrough solutions are combined with standard, modular components [26]. Looking at the applications areas in Fig. 1, the diagnosis, the monitoring and the control of medical devices look more feasible in the short run. An integrated application which includes the surgery provides more outsized potential for benefit. The personalized medicine should be emphasized by researchers again in ordert o apply digital twin.

Digital Twin is an appropriate mean to provide an architectural basis for further development of a medical device in terms of device's efficiency, safety and risks. A conceptual approach for the generation of a Digital Twin of a medical device was presented here based on an architectural 4x4 matrix. A use case for the on-board auxiliary battery was presented for purpose of demonstration. In a similar way, a Digital Twin for further modules and entire products can be generated under the PLM system. It puts forward the current applications of digital twins in healthcare, summarizing that DTs are most popular in the personal health management and precision medicine, with the core of DTs in healthcare being how to collect, harmonize, integrate, and analyze data [14].

A transdisciplinary approach, to consider all the involved aspects, from technical knowledge, to personnel management to economics and innovation is a key factor to ensure the full exploitation of the medical devices potential. The apex of the DT implementation which is possible to this day represents a fully semantic DT, leveraging acquired knowledge with the use of AI-enabled agents. Optimisation would be fully entrusted to the DT's goals and learning patterns. Enabling a user-driven experience is mandated, where the DT can adapt to social requirements and engage with end-users to support holistic decision-making. Actuation of the environment becomes fully autonomous to the DT system, requiring human supervision [18].

#### References

- M. Grieves, J. Vickers, Digital Twin: Mitigating Unpredictable, Undesirable Emergent Behavior in Complex Systems, in: F.J. Kahlen et al. (eds.) *Transdisciplinary Perspectives on Complex Systems: New Findings and Approaches*, Springer International, Cham, 2017, pp. 85-113.
- [2] N.N., Digital Twins for Industrial Applications. Definition, Business Values, Design Aspects, Standards and Use Cases, An Industrial Internet Consortium White Paper, Version 1.0, 2020-02-18, <u>https://hub.iiconsortium.org/portal/Whitepapers/5e95c68a34c8fe0012e7d91b</u>, accessed Mar 5<sup>th</sup>, 2022.
- [3] K.Y. Hong Lim, P. Zheng and C.H. Chen, A state-of-the-art survey of Digital Twin: techniques, engineering product lifecycle management and business innovation perspectives, *Journal of Intelligent Manufacturing*, 2019, https://doi.org/10.1007/s10845-019-01512-w.
- [4] M. Perno, L. Hvam, Developing a Framework for Scoping Digital Twins in the Process Manufacturing Industry, Advances in Transdisciplinary Engineering, 2020, Vol. 13, pp. 475-486.
- [5] C.K. Lo, C.H. Chen, R.Y. Zhong A Review of Digital Twin in Product Design and Development, Advanced Engineering Informatics, 2021, Vol. 48, 101297.
- [6] M. Sommer, J. Stjepandić, S. Stobrawa and M. von Soden, Automated Generation of Digital Twin for a Built Environment Using Scan and Object Detection as Input for Production Planning, *Journal of Industrial Information Integration*, 2022, in press.
- [7] H. van der Valk, H. Haße, F. Möller, M. Arbter, J.L. Henning, B. Otto, A Taxonomy of Digital Twins, in: B. Anderson, J. Thatcher, & R. Meservy (eds.), *Proceedings of 26th Americas Conference on Information Systems*, 2020, pp. 1-10.
- [8] A. Biahmou, T. Majić, J. Stjepandić, N. Wognum, A platform-based OEM-supplier collaboration ecosystem development, *Advances in Transdisciplinary Engineering*, 2019, Vol. 10, pp. 436-445.
- [9] N. Wognum, C. Bil, F. Elgh, M. Peruzzini, J. Stjepandić and W.J.C. Verhagen, Transdisciplinary systems engineering: implications, challenges and research agenda, *International Journal of Agile Systems and Management*, Vol. 12, 2019, No. 1, pp. 58-89.
- [10] MN. Kamel Boulos, P. Zhang, Digital Twins: From Personalised Medicine to Precision Public Health. *Journal of Personalized Medicine*, 2021, 11(8):745. https://doi.org/10.3390/jpm11080745.
- [11] Y. Liu, L. Zhang, Y. Yang, L. Zhou, L. Ren, F. Wang, R. Liu, Z. Pang, M. Jamal Deen, A Novel Cloud-Based Framework for the Elderly Healthcare Services Using Digital Twin, *IEEE Access*, 2019, Vol. 7, pp. 49088 49101, DOI: 10.1109/ACCESS.2019.2909828.
- [12] M. Gupta, G. Chaudhary, V.H.C. de Albuquerque, Smart Healthcare Monitoring Using IoT with 5G Challenges, Directions, and Future Predictions, CRC Press, Boca Raton, 2022.
- [13] C. Boccato, S. Cerutti, J. Vienken, Medical Devices: Improving Health Care Through a Multidisciplinary Approach, Springer Nature Switzerland AG 2022.
- [14] D. Yang, H.R. Karimi, O. Kaynak. S. Yin, Developments of digital twin technologies in industrial, smart city and healthcare sectors: a survey, *Complex Engineering Systems*, 2021;1:3,ces.2021.06
- [15] X. Zheng, J. Lu, D. Kiritsis. (2021) The emergence of cognitive digital twin: vision, challenges and opportunities. *International Journal of Production Research* 0:0, pp. 1-23.
- [16] J. Guo, Z. Lv, Application of Digital Twins in multiple fields, *Multimedia Tools and Applications*, 2021, https://doi.org/10.1007/s11042-022-12536-5.
- [17] P. Zheng, H. Wang, Z. Sang, R.Y. Zhong et al. Smart manufacturing systems for Industry 4.0: Conceptual framework, scenarios, and future perspectives. *Frontiers of Mechanical Engineering*, 2018, Vol. 13, pp. 137–150, https://doi.org/10.1007/s11465-018-0499-5.
- [18] C. Boje, A. Guerriero, S. Kubicki, Y. Rezgui, Towards a semantic Construction Digital Twin: Directions for future research, *Automation in Construction*, Vol. 114, 2020, 103179.
- [19] C. Emmer et al., Advanced engineering visualization with standardized 3D formats, *IFIP Advances in Information and Communication Technology*, Vol. 409, Springer, Berlin Heidelberg, 2013, pp. 584-595.
- [20] P.J. Ogrodnik, Medical Device Design: Innovation from Concept to Market, 2nd ed, Elsevier, London, 2020.
- [21] E. Ostrosi, J. Stjepandić, S. Fukuda and M. Kurth, Modularity: New trends for product platform strategy support in concurrent engineering, Adv. in Transdisciplinary Engineering, 2014, Vol. 1, pp. 414-423.
- [22] J. Masison, J. Beezley, Y. Mei, HAL Ribeiro, A. C. Knapp and al., A modular computational framework for medical digital twins, *Proceedings of the National Academy of Sciences*, 2021, 118(20), e2024287118.
- [23] O. Kuhn, H. Liese and J. Stjepandic, Methodology for knowledge-based engineering template update, *IFIP Advances in Information and Communication Tech.*, Vol. 355, Springer, Berlin, 2011, pp. 178-191
- [24] N.N., Multi-purpose platform for biosensing, <u>http://bitalino.com/en/</u>, accessed, March, 15 2022.
- [25] A. Ahluwalia, C. De Maria, A. Díaz Lantada, Engineering Open-Source Medical Devices: A Reliable Approach for Safe, Sustainable and Accessible Healthcare, Springer Nature Switzerland AG, 2022.
- [26] E. Ostrosi, S. Sagot, Modularity and configuration applied to product integrating the IoT technology, Advances in Transdisciplinary Engineering, Vol. 12, pp. 602-611 (2020).