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A Multi-Stakeholders Co-Design Methodology Applied to an Insulin Pump Mechatronic System

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Abstract— Nowadays Cyber-Physical-Systems (CPS) are becoming more and more complex, and involve a large number of stakeholders. They all have a different but significant role at a certain phase of the system lifecycle, and they all have an influence on the CPS specifications. This paper gives an overview of a co-design methodology that aims at assisting multiple stakeholders, having concerns about a common system, to agree on sets of objectives and mutual obligations. The objective here is to identify the requirements that fulfill the intrinsic goals of each stakeholder. The agreements among stakeholders are introduced into formal contracts to enable their formal verification. The methodology was successfully applied to a large energy system of systems. This paper discusses its application to a smaller system which is the insulin pump.

Keywords— Cyber-Physical-Systems, mechatronics, stakeholders, system lifecycle, co-design, methodology, requirements.

I. INTRODUCTION

Nowadays Cyber-Physical-Systems (CPS) are becoming more and more complex, and involve a large number of stakeholders, all of whom have a significant role at a certain phase of the system lifecycle. Thus, they all got the capacity to influence the requirements of a CPS. Given the nature of their role, their culture and their field of expertise, stakeholders have different views regarding the same system and have a hard time agreeing on common objectives. At early conceptual phases of CPS, each stakeholder that is involved or concerned by a system has intrinsic interests and goals that can widely differ regarding his viewpoint. In a context where everyone seeks to maximize its own profit, and where the benefits of a stakeholder are inversely correlated with others interests, we generally find ourselves facing contradictory expectations and different perceptions regarding the same system. Stakeholders have no means to assist them to overcome this challenge.

In this context, we have introduced a methodology that allows stakeholders to be coordinated for the sake of identifying a common ground to meet everyone's expectations.

This methodology is based on multiple modeling layers that allow having at the same time a view that is centered on stakeholders in parallel with a “System” view on the CPS. The idea is to have a clear definition of stakeholders' intrinsic interests, their interactions regarding others and at the same time to have means to work on a system level and make

modeling and simulation. It would allow stakeholders to make well-informed negotiations.

This methodology was conducted as part of an industrial project in the energy sector. It was applied to a large complex multi-energy system including a large number of stakeholders [1]. Encouraging results were achieved within the application of the methodology.

We have later asked ourselves whether this methodology was appropriate to smaller mechatronic systems. Indeed, one can underestimate the complexity of the development of small mechatronic CPS such as insulin pumps. On the contrary, such systems also involve a large number of disciplines and stakeholders having different cultures and coming from independent entities. Thus, they have different goals and constraints. Agreeing on common objectives is also a considerable challenge. The stakeholders need to mutually agree on the appropriate system specifications to have better chances to come up with a successful design that answers the real need of stakeholders.

In this paper, we take the example of an insulin pump or so-called “Artificial Pancreas”.

The paper is organized as follows. Section II provides an overview of the related works. A description of the methodology is introduced in section III. It is then applied to the insulin case study in section IV. Finally, a conclusion is given in section V.

II. STATE OF THE ART

In literature, the idea of correctly capturing stakeholders' needs is commonly recognized as a critical success factor of complex systems. The stakeholder theory introduced by Freeman in [2] emphasizes the necessity for a company to take into consideration ethical and social aspects in decision making. For that end, the company needs to analyze its impact on the external stakeholders and vice versa by classifying them into different categories and acting in consequence.

Systems Engineering (SE) repositories such as [3] propose among the processes the “Stakeholder needs and requirements definition” as one of the first activities that need to be meticulously analyzed as it is considered as the basis of all the processes that follow.

State of the art methodologies such as [4], [5], [6] only considers the stakeholders of a system as a source of requirements which are identified in early design phases. Thereafter, the methodologies provide processes and activities

that aim at refining the stakeholders' needs in order to design the system that best answers the stakeholders' intents. The limitation here is that the establishment of stakeholders' requirements are generally set up from a unique designer point of view in the initial design phases, and are rarely revisited. However, in an industrial context, stakeholders have requirements that evolve all along with system development. The requirements are constantly refined and reevaluated by stakeholders at different development steps, especially for large Systems of System (SoS) where negotiations between stakeholders can take place. A correct definition of stakeholders' needs is thus a challenge by itself and requires in-depth analysis.

III. METHODOLOGY OVERVIEW

A. Preamble

The methodology introduced aims to define a framework that assists CPS stakeholders to negotiate and agree on mutual contracts that will answer the needs of all parties.

Our methodology is based on multiple layers with a stakeholder-centric description, as shown in Fig. 1. They consist on the one side of modeling the elements that are intrinsic to each stakeholder, thus representing its goals, role and behavior. On the other side, they consist of modeling the relationships and interactions between the stakeholders. These elements aim essentially at precisely specifying the perimeter and obligations of each stakeholder. They afford a collaborative framework where stakeholders can make "well informed" negotiations.

Five modeling layers are essentially defined in the methodology. For the purpose of developing executable verification models, we use the concepts of "Observer" and "Binding" added for connecting the heterogeneous models from different layers, notably the formal requirements, architectural models, and behavioral models.

The following section introduces the five modeling layers.

B. Intentional level

In this methodology, and contrary to the classical approaches that take as a starting point the missions of a system and its technical constraints, we start here from the intentional level of stakeholders. In this level, we will capture the high-level objectives of the stakeholders.

In the most abstract level of stakeholders' goals, which refers to their main reason for being involved in a CPS, the requirements or interests come down to a small number of needs and can be described with only a few words. They are generally limited to financial aspects for companies, to the well-being of consumers, and social and political aspects for governments. Afterward, they are declined through multiple decomposition layers into more elementary concepts and means-ends in order to reach high-level goals.

Starting from such an abstract level allows identifying the real needs of stakeholders instead of jumping into the solution world. It also ensures the traceability for the large number of specifications that emerge all along the system development.

The definition of the intentional level of our methodology was widely inspired by the work of Eric et al. in [7]. The latter puts forward a characterization using natural language blocks as well as a formal one. Our methodology only considers the natural language description blocks of the intentional level.

We have considered a different approach for their formal characterization.

The intentional level is based on two main models:

- The stakeholders' dependency model captures the dependencies between stakeholders where a stakeholder can be a "dependor" when depending on another party, or a "dependee" when a party is depending upon him. The object of the dependency is called the dependum. Fig. 2 shows the four types of dependencies between a stakeholder X and a stakeholder Y. The direction of the arrays goes from the dependor to the dependee. This means here that the stakeholder X depends on the stakeholder Y regarding the goal G , the task T , the resource R , and the soft-goal SG .
- The stakeholder rationale model can be considered as a justification model that describes the reasons behind the dependencies of a stakeholder regarding others. The high-level goals of stakeholders and their roles and captured in this model and are decomposed through multiple steps using four elements Goal, Soft-Goal, Task, and Resource.

C. Properties formalizing level

In this level, the stakeholders' needs as well as the requirements related to the dependencies are formalized. Requirements formalizing is done using the requirement language named FORM-L (FOrmal Requirements Modeling Language) [8]. The objective of this level is defining from the one side the Key Performance Indicators (KPIs) under which stakeholders will make their future decisions. These KPIs will be part of the stakeholder description and are not intended to be shared with others. From the other side, the objective is to formally define the obligations of each stakeholder regarding others. These obligations will be integrated into the formal contracts that bind them and will be subjected to modifications all along the negotiations. The formal contracts are considered here to be the interfaces between stakeholders. They define the degrees of freedom of each of its contractors. This is a strong property that will allow each stakeholder to make an abstraction of the real behavior of his environment and work separately. The contract guarantees an envelope covering all possible behaviors of other stakeholders.

D. Stakeholders interaction model

In this methodology, we have chosen to distinguish between the interactions among stakeholders and the interactions among the systems under their responsibility, even though they are strongly interdependent. Indeed, it seemed crucial in this methodology to have a dedicated model for the interactions between the stakeholders because some aspects such as financial transactions or administrative processes are more related to stakeholders than systems. Such aspects have a considerable influence on the choices that are made at the system level. It is thus important to identify the relationships between the two levels for a good decision making.

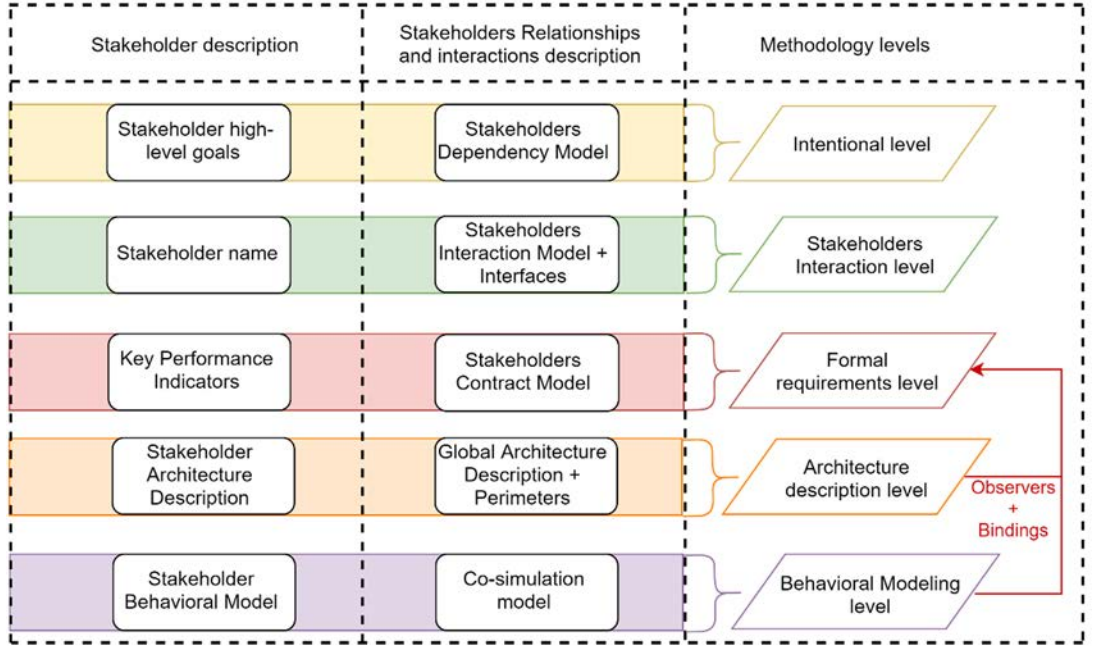


Fig. 1. Methodology modeling layers

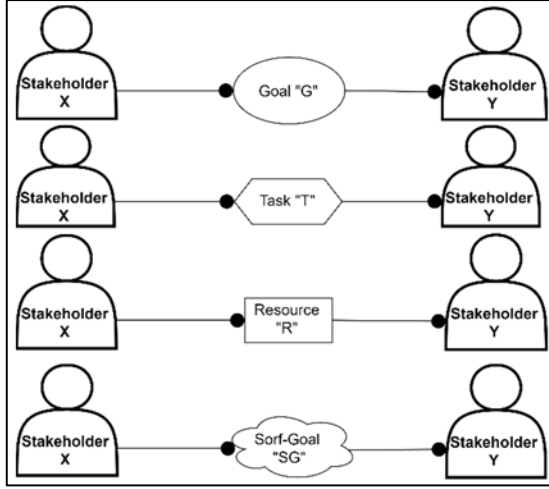


Fig. 2. Types of dependencies

This modeling level consists of a set of nodes representing the stakeholders and a set of arrays that represent what is the nature of the interaction between stakeholders, and in which direction. The interactions here must be characterized using four elements: the resource being exchanged, the means of exchange, the protocol of exchange and the rules of the exchange. Detailed modeling of these aspects can be developed as part of the behavioral modeling layer. This model stem from the intentional level where we identify all the dependencies between stakeholders. Indeed, the resource dependencies between stakeholders are translated and characterized more deeply in this level.

E. Architecture description

The architecture description layer was mainly introduced in order to have a "system" view of the developed CPS by bringing to the fore the dynamic interactions between the subsystems under the responsibility of different stakeholders. Similarly to the level above, the interactions are characterized using the four elements the resource being exchanged, the means of exchange, the protocol of exchange and the rules of the exchange.

This view does not preclude the inclusion of the stakeholder aspect. In fact, we have introduced the concept of "perimeter" in the architecture description. The perimeter is used to define the scope of responsibility of each stakeholder. This perimeter is subjected to modifications all along the development phases of the system. Negotiations between stakeholders will have a considerable influence on the definition of the perimeter. The architectural description included in the perimeter of each stakeholder is later introduced into this stakeholder description model.

F. Behavioral modeling level

This level only deals with one dimension, the behavioral description of the system under the perimeter of each stakeholder. In this layer, stakeholders have the freedom to model their behaviors using different modeling languages and tools. Throughout the different steps of the engineering lifecycle, different kinds of behavioral models will be used by engineers. In preliminary studies, stochastic models are more likely to be used as only a few is known about the system. In design phases, static or dynamic behavioral models based on Differential-Algebraic Equations (DAE) can be used for system sizing. In detailed design phases, 3D models, Computational Fluid Dynamics (CFD) and similar paradigms are used to have a system representation that is close to its real performances once produced.

We do not consider in this methodology that the behavioral models of stakeholders are shared with the others. We are aware that they represent a precious knowledge for parties. However, according to the context, stakeholders can share their models or make co-simulation for a better assessment of the overall system.

G. Verification Model

In order to find mutual agreements between stakeholders and set up formal contracts, parties need to check on the one side that the contract requirements satisfy their high-level need, on the other side, that they have the capacity to commit to their obligations. To that end, we have introduced a verification level into the methodology. This layer allows

stakeholders to make all kinds of testing using modeling and simulation.

The architecture of the verification model used in this methodology was first introduced in [9].

Two main concepts are used for setting a verification model: Observers and Bindings. The observers and bindings allow connecting the behavioral models, architectural models, and the formal requirement models for the purpose of making executable verification models. In fact, these models are from different natures and are generally developed by engineers from different disciplines with different backgrounds. The observers, as their name suggests, are used to observe and capture data from the dynamic behavior simulated using the disciplinary models. They also capture engineering data from the architectural description model. The observers have a second role which is transforming the data in order to be consistent with the inputs of the requirement model. The bindings allow connecting the heterogeneous models mentioned above including the observation models.

IV. CASE STUDY

In order to evaluate the appropriateness of our methodology regarding mechatronic systems, we have set up a reflection on the insulin pump example. The idea is to propose a framework for the concerned stakeholders to converge towards mutual agreements answering the needs of everyone.

A. Insulin pump: a CPS and mechatronic case study

An insulin pump, or “artificial pancreas”, is a mechatronic device that contributes to solving diabetic patients' constraints [6], [10]. Indeed, in order to deal with diabetes, an artificial corrective process is necessary to improve a biological defective process, quantified by the glucose level, with an automated dosage of injected insulin. This closed-loop insulin delivery system consists of three main blocks, which are an “Insulin Dispensing Device” (pump, catheter, and cannula), a “Continuous Glucose Monitoring” (a sensor placed on the skin), and a control algorithm implemented in an embedded system. The system energy autonomy and its ergonomics are important. Moreover, it has to be connected to a smartphone, a computer, and a medical network. Thus, it is a CPS with important human, energetic, safety, and security concerns.

B. Methodology application

In the early conceptual phase of the insulin pump development, the high-level interests of each stakeholder are defined.

For this case study, we consider the following stakeholders:

- Patients: considered to be diabetic.
- Doctors: are in charge of the medical monitoring of the patients.
- Health insurers: are in charge to repay a part of the expenses to patients.
- Government: is in charge of making the medical laws and standards, and give certifications.

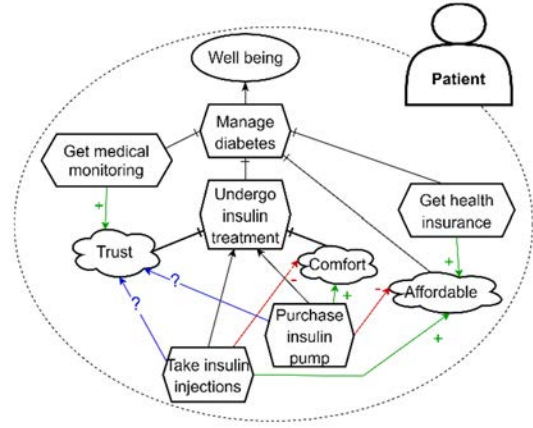


Fig. 3. Patient strategic rationale model

- Insulin supplier: is in charge of the supply of insulin.
- Vendors: are in charge of selling insulin pumps to patients.
- Designer - Producer: is in charge of the development and the production of the insulin pump.

Although this list of stakeholders is not exhaustive, it already contains a considerable number of parties that need to agree on mutual requirements. In addition to these stakeholders, we consider the environmental constraints that will be taken into account in a specific contract. Once the stakeholders converge towards mutual contracts, we assume that the objectives of the methodology were attained.

1) *Intentional level*: The first step of the methodology is to capture the high-level intentions of each stakeholder as well as stakeholder dependencies. In the following, we will describe the intentions of the patient and the designer.

Fig. 3 shows the strategic rational model of the patient. His main high-level goal is his well-being. This goal is achieved by the task “Manage diabetes” which in turn is broken down into three sub-tasks: “Get medical monitoring” by the doctor, “Undergo insulin treatment” and “Get health insurance” to help to support the induced medical expenses. “Manage diabetes” is associated with a soft-goal “Affordable”. There are two alternatives for the patient to have insulin treatment: either to get the classical insulin injections or to purchase an insulin pump that will substitute the manual injections.

The insulin treatment induces two soft-goals: “Comfort”, and “Trust”. The final choice of the patient among the different alternative solutions will be guided by the above-mentioned soft-goals.

The second step of the intentional level is the identification of the different dependencies between stakeholders. These dependencies will allow stakeholders to achieve their high-level goals by relying on other parties to perform the tasks they cannot achieve on their own.

Fig. 4 represents the different dependencies among the stakeholders. The dependencies related to the fulfillment of the patient's intentions are highlighted in red.

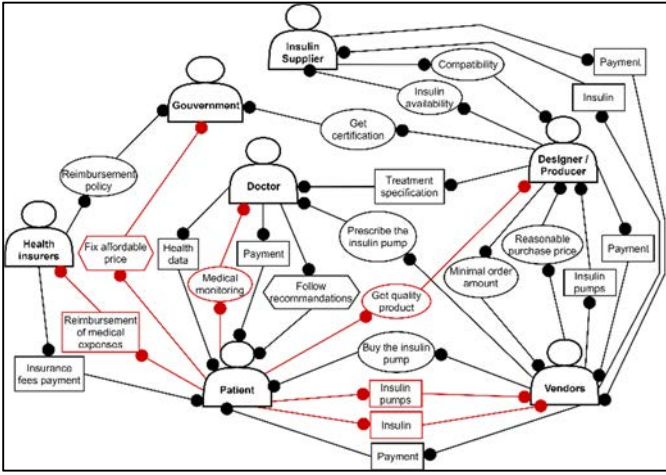


Fig. 4. Stakeholders dependency model

For instance, the patient depends on the doctor to “Get medical monitoring” which is a sub-task derived from his high-level goal of “Well being”. This dependency is represented by a *goal dependency* having an elliptic shape labeled “Medical monitoring” in Fig. 4. He also depends on the Designer/Producer to get a quality product that contributes to the fulfillment of the “Trust” and “Comfort” soft-goals.

2) *Stakeholder interaction model*: In this phase, the interactions between stakeholders are captured. Fig. 5 shows three types of exchanged elements between stakeholders, notably: financial transactions, data transfer, goods transfer. When comparing with Fig. 4, we can see that the resource dependencies between stakeholders are translated here into interactions.

3) *Formalizing properties level*: In this level, the properties defined in the intentional level are formalized by:

- deriving Key Performance Indicators (KPIs) from the high-level needs of stakeholder,
- establishing contracts containing formal requirements related to the dependencies between stakeholders. These formal requirements can be automatically verified later on.

In the intentional description of the patient, three main soft-goals were identified: “Affordable”, “Comfort” and “Trust”. Obviously, all patients do not have the same view and the same priorities. However, all kinds of patients need to be represented. The soft-goals above-mentioned form a decision triangle where the patients can set the cursor in different positions according to their view.

These aspects can be formalized with:

- Affordable = The extra amount to be paid for the pump must not exceed X percent of the medical fees of the standard treatment.
- Comfort = (i) The size of the pump must not exceed the dimensions $A*B*C$ mm³ (ii) the weight of the pump must be less than the weight M g, (iii) the frequency of battery change must be less than Nb times a year, (iv) the insulin refilling must be less than Ni times a month.

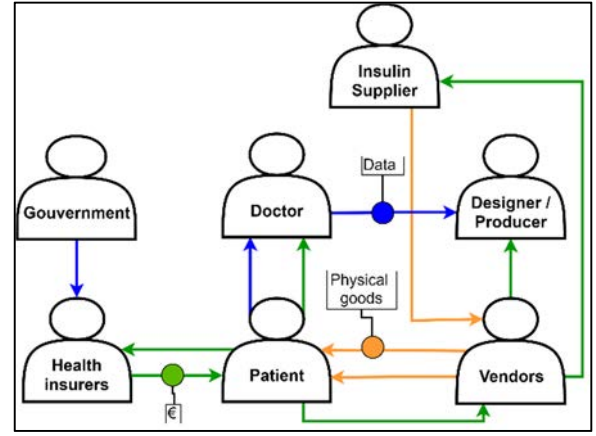


Fig. 5. Stakeholders interaction model

- Trust= The insulin pump must have an accuracy of Pr mg and must not derive from it more than once a year. When it does, an alarm should be sent to the patient and the doctor.

From the designer side, the KPIs will be derived from the two soft-goals “Be profitable” and “Be competitive” and the goal “Gain market share”.

- Be profitable = The annual revenue from the activity must be higher than P percent of the sales revenue
- Be competitive = The price of the insulin pump must be lower than at least C percent compared to its competitors when the product will be placed on the market.
- Gain market share = The market share of the insulin pump must increase with Z percent per year for the two first years.

We emphasize that the formal properties can be defined in different manners, and the choices of the KPIs can widely vary depending on the intentions of the stakeholder. For instance, the formal characterization of “Being competitive” could have been defined using a market share indicator.

Similarly to the patient and the designer, the formalizing was done for the other stakeholders.

In order to establish contracts between stakeholders, the dependencies between them were formalized. For instance:

- The goal dependency “Reasonable purchase price” of the vendors regarding the designer/Producer will induce the requirement: The purchase price of the insulin pump must be lower than the threshold P_{max}
- The resource dependencies “Insulin pumps” and “Insulin” of the patients regarding the vendors will induce requirements regarding the availability of these resources.

4) *Architecture description*: The architecture description level was developed in order to have a “System” view on the CPS by identifying the interactions between sub-systems and defining the perimeters of the concerned stakeholders.

In the current case study, the dynamic interactions between systems are mainly (i) the interactions between the components of the insulin pump, (ii) the interactions between the insulin pump and the body of the patient (iii) and the data

exchanged between the insulin pump and the doctor monitoring device.

5) *Behavioral modeling*: In this level, stakeholders develop the behavioral models of the system under their perimeter for subsequent verification.

In order to attain his goals, the designer needs to develop behavioral models that would allow him to assess whether if the development of the insulin pump satisfies his KPIs such as profitability. To that end, the designer will develop a preliminary financial model that considers the pre-sizing of the insulin pump and the conceptual solutions to be considered.

In the design phases, the designer will develop dynamic physical models coupled with I&C representing the behavior of the different components of the insulin pump. These models will allow him to make a detailed design, and they used latter in the verification model.

Similarly, other stakeholders develop behavioral models representing their systems in order to help them make the decisions that answer the most their needs.

6) *Verification model*: Verification models are built using elements from the different levels introduced earlier. From the designer's view, the first verification model to develop would aim to check if the preliminary architecture of his insulin pump is coherent with his KPIs and the contracts regarding other stakeholders. For that purpose, the designer gathers the following elements (i) the financial computation model (ii) the architecture description of the insulin pump that contains the first estimations of the elements costs, for different possible technologies, (iii) the KPIs model with the requirements that are related to the profitability, and (iv) the formal contracts with the other stakeholders including their requirements.

Other verification models are established throughout the other design phases including behavioral models that are representative of the reality and requirements that are more specific on what the system shall do and how it should perform.

V. CONCLUSION

In this paper, we have presented a co-design methodology that assists multiple stakeholders of a CPS to converge towards common specifications and objectives. The idea is to elaborate together formal contracts specifying the obligations of each of its signatories.

The particularity of this methodology is that it combines two complementary views: a view that is centered on stakeholders, and a view that allows having a "System" view

on the CPS. Throughout its different modeling layers, the methodology offers means to have design traceability at every development phase with justification element all along.

The application of the methodology to the mechatronic system "insulin pump" was worthwhile as it allowed us to test whether the methodology can be applied to other domains than the energy sector for which it was initially built. This application have given us promising results to test the methodology on other sectors having the common challenge of stakeholders' coordination.

However, one of the methodology layers turned out to be not very accurate for mechatronic systems, notably the architecture description level. The goal of this level was above all to identify the perimeters of each stakeholder and the interactions between them in operational phases. In the insulin pump case study, only a few interactions between systems were identified. The systems being under the responsibility of different stakeholders. However, this does not question the adaptability of the approach for mechatronic systems.

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