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# Ventricular Assist Device in Health 4.0 Context

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**Abstract.** In the current digital era, the physical world has a cyber-representation. Both the real and virtual worlds are connected in areas, such as informatics and manufacturing. This phenomenon is currently emerging in health applications. Health 4.0 (H4.0) refers to a group of initiatives aiming to improve medical care for patients, change the business practices of hospitals and create new insight for researchers and medical device suppliers. Increasing collaboration in terms of physicians, medical equipment, artificial organs, and biosensors is a way to facilitate H4.0. In this work, a reference architecture model for Industry 4.0 (RAMI 4.0) is used to support such collaboration in medical devices control system projects. A methodology was applied to design a ventricular assist device. The results show that RAMI 4.0 is an adequate technique for modeling a device as a H4.0 component. Future works should implement the designed control system.

**Keywords:** Health 4.0, Industry 4.0, RAMI 4.0, Control System, Ventricular Assist Device, VAD.

## 1 Introduction

A discussion regarding future trends in health equipment, artificial organs and biosensors is required for interoperability aiming to improve medical care for patients, change the business practices of hospitals and create new insight for researchers and medical device manufacturers [1].

In fact, in some industries, this practice, which is called digital and cyber convergence, has already been established, and the cyber-physical systems (CPS) or the Internet of Things (IoT) are the main technology used. Both are the basis of Industry 4.0 (I4.0) in manufacturing and digital convergence in informatics [2].

Based on the I4.0 concept, Health 4.0 (H4.0) has been derived according to the health domain. Connected sensors with cyber representations will be used more frequently and connected devices may be used to track patients or measure vital signs in the future with H4.0. For instance, an algorithm was developed to estimate arterial blood pressure with a noninvasive photoplethysmography sensor, and the estimated pressure is presented via a smartphone or smartwatch [1]; The Food and Drug Administration

(FDA), which is the American department responsible for medical equipment, has already approved some applications for iPhones and iPads with self-diagnostic and self-prognostic capabilities [3]; A telemedicine system structure oriented by service was proposed and implemented [4]. However, developing a standard for the use of this type of device is important for interoperability, the creation of more services and improving patients' quality of life.

Was not found in literature a Reference Architecture Model for Health 4.0. The IEC 62264-1:2013 standard (Enterprise-control system integration: Models and terminology) was used as an architecture model reference to develop control systems early in industry, and later in health [5]. However, the IEC 62264 standard alone is insufficient for modeling control systems in connected applications that requires that level of interoperability and collaboration.

### 1.1 RAMI 4.0

To develop an uniform architecture model as a reference, Plattform Industrie 4.0, which is a German organization responsible for developing and promoting I4.0, proposed the Reference Architecture Model Industrie 4.0 (RAMI 4.0) in 2015 [6].

RAMI 4.0 (as shown in Fig. 1) is a three-dimensional model used to represent the I4.0 components. RAMI 4.0 supports novel research in manufacturing as follows a study describes the machine controller as an I.40 component [7]. Pisching et al. proposed a method to create an architecture based in RAMI 4.0 and applied it to develop a system which a smart product discover an equipment to be manufactured [8]. RAMI 4.0 is based on the IEC 62264-1:2013 (Enterprise-control system integration: Models and terminology), IEC 61512-1:1997 (Batch Control: Models and terminology) and IEC 62890:2016 (Enterprise-control system integration: Models and terminology) standards [9] and was inspired in the smart grid architecture model (SGAM), a framework for design projects in smart grid domains [6].

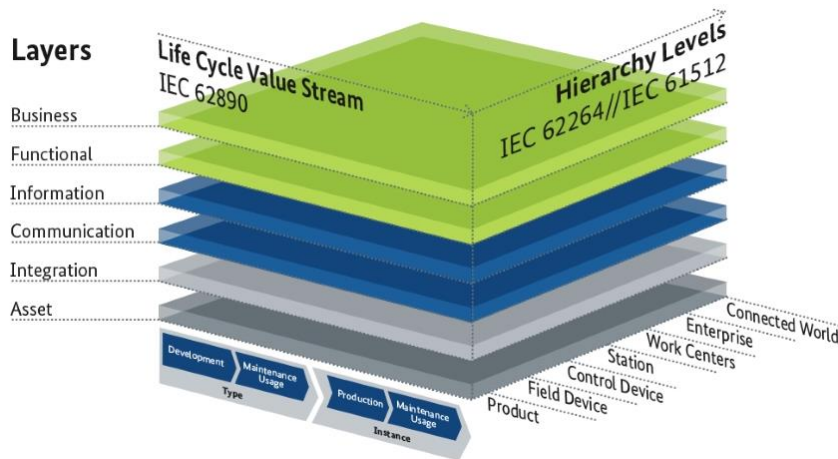
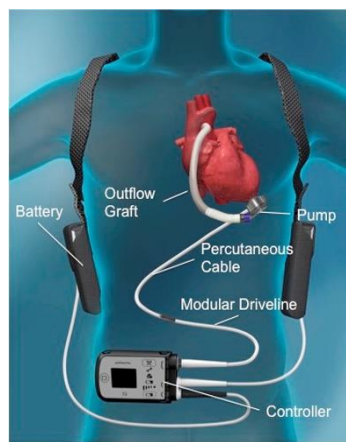


Fig. 1. Reference architecture model for Industry 4.0 (RAMI 4.0) [6].

## 1.2 Ventricular Assist Device

Recently, ventricular assist device (VAD) therapy has emerged as an alternative for heart transplantation for heart failure patients. However, some adverse events, such as bleeding, stroke, and aortic insufficiency, still occur in VAD patients. Based on the hypothesis that a physiologically controlled VAD can prevent some of these events, various concepts of physiological controllers have been developed over the last decades [10–14].

VAD consist in pump with motor, controller, outflow, driveline cable and batteries as show in Fig. 2.



**Fig. 2.** Ventricular Assist Device (VAD) [15].

The aim of the current study is design a VAD control system in H4.0 context. For reach interoperability, collaboration and connected requirements RAMI 4.0 was used.

## 2 Contribution to Life Improvement

According World Health Organization, 32,3 million people will die in 2060 in consequence of circulatory system disease [16]. Heart failure is a serious healthcare issue and affect about 23 million people worldwide [17]. With heart failure, the main organ cannot pump enough blood for body. Ventricular Assist Device (VAD) operates together with the natural heart, decreasing the mechanical work of the myocardia required to pump blood in patients with severe heart diseases. VADs are centrifugal pumps. VAD had already increased survival of more than 40,000 people [18, 19], but only 30% of VAD patients are free from any adverse events [20]. Physiological system control could solve adverse events, nevertheless is a big challenge [10–14].

Schlöglhofer et al. proposed a standard call every two weeks for a group of VAD patients during one year. Comparing with the control group without call, the group with call intervention increased survival from 59% to 89% after 2 years [20].

It believes that increase survival also if physicians analyze current and stored VAD data. A cloud connected control system for a VAD has been implemented. Based on hypothesis that physicians could improve the life of patients with remote management of VAD data, a connected VAD could send the telemetry data to a cloud platform.

IoT is used in other industries to bring device data to a cloud platform, nevertheless the device must be describe as an IoT component. According Plattform Industrie 4.0, in manufacture, to connect an IoT device in a cloud service, is necessary to describe it as an I4.0 component using RAMI 4.0 [6].

RAMI 4.0 going to be used to describe and implement a cloud connected VAD control system. RAMI 4.0 could be used also to design other H4.0 components. That H4.0 components could be used to collaborate together with physicians and improve life of patients.

### 3 Methods

A VAD control system architecture that store data in cloud was designed. The proposed architecture was described as a H4.0 component using RAMI 4.0. Method proposed by Pisching et al. [8] was used to describe it.

That method consists:

- 1) Describe components function shared by layer;
- 2) Draw components as blocks in 3D model RAMI;
- 3) Conceptual and functional modeling of the processes using PFS/MFG technique.

For that study steps 1 and 2 was conducted. “Life cycle Value Stream” axe of RAMI 4.0 was not considered.

Technique proposed for Leão et al. [21] was used as basis for VAD local control system.

### 4 Results

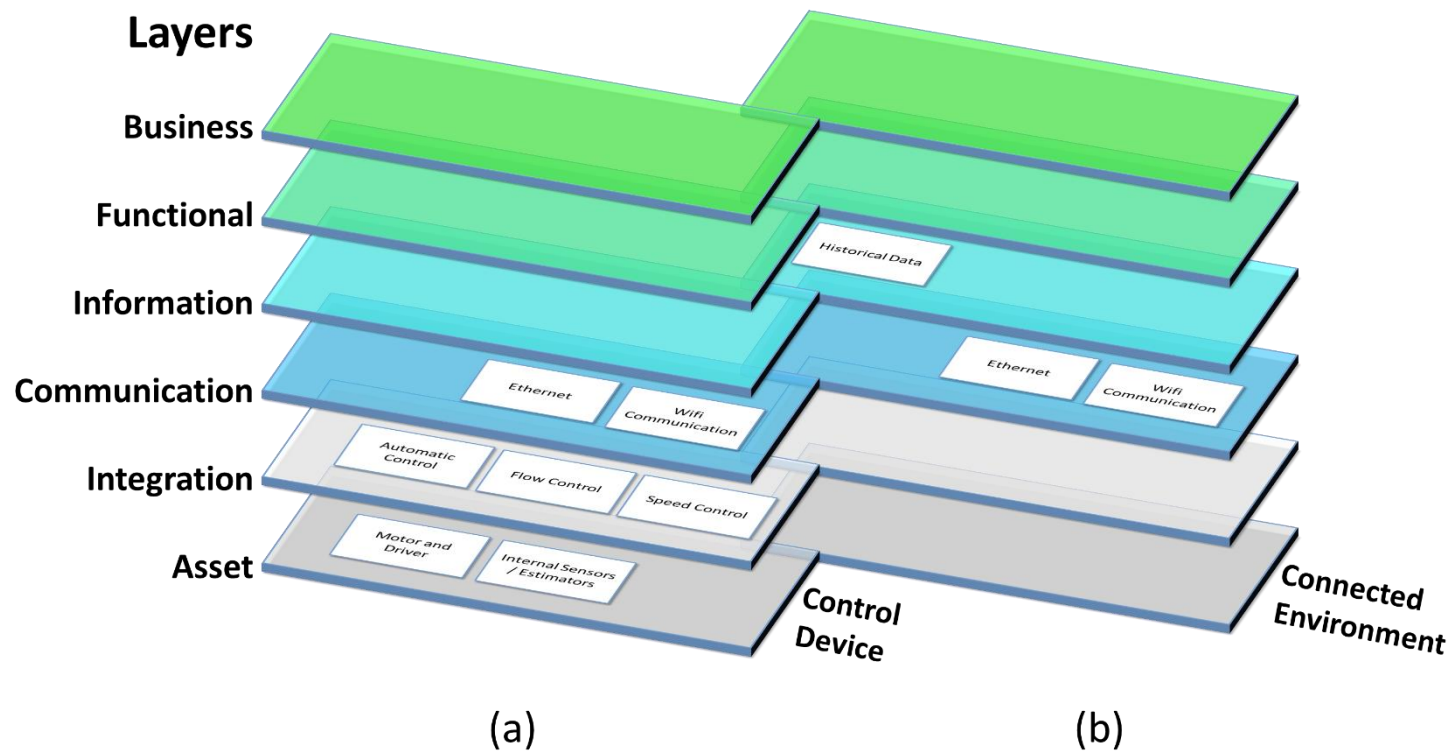
A connected VAD can send data to a cloud platform to improve the patients’ life quality.

Follow specifications, a standard VAD has a motor, integrated current sensor, pressure and flow estimators, speed control, flow control and automatic control [21]. To render VAD a H4.0 component, the VAD has also a historical data in cloud for storage VAD and patient data.

In this study, the life cycle axis was not considered in developing the VAD. The hierarchy levels control device, and connected environment were considered.

#### 4.1 Control Device

The “Control Device Hierarchy” components are shown in Fig. 3 (a). The “Control device hierarchy” / “Asset” layer was developed with two components:



**Fig. 3.** VAD Control system proposed by Leão et al [21] described as a H4.0 component. (a) Control device agents. (b) Connected Environment agents.



- Motor and Driver – That is the hardware in charge to transfer movement to VAD pump. Its input is a voltage of motor speed and outputs are voltage of real speed and motor current.
- Internal Sensors and Estimators – That are other sensors build in local control system. In that case flow, pressure and heart beat estimators.

The “Integration” layer contain three components:

- Speed Control – It is a component responsible for updates voltage to “Motor and Driver” and receives speed setpoint from “Flow Control”.
- Flow Control – It receives flow setpoint from “Automatic Control” component and provides speed setpoint to “Speed Control” component.
- Automatic Control – It is a Fuzzy Logic System that receives status of patient from physician, receives data from “Internal Sensors and Estimators” and suggests flow setpoint to “Flow Control”.

The “Communication” layer consist of two components: “Ethernet” and “Wi-Fi” to bring connectivity to the device.

## 4.2 Connected Environment

The connected environment hierarchy has the same previously discussed communication components (“Ethernet” and “Wi-Fi”), including “Historical Data” component in the “Information” layer.

“Historical Data” is a database to maintain information related of device and patient. Fig. 3 (b) shows the connected environment hierarchy agents.

## 5 Conclusions

Health 4.0 has been widely studied and can improve the healthcare system. A reference architecture model is already used in the energy and manufacturing industry; thus, RAMI 4.0 can also be useful for developing medical device projects. The application in VAD design shows that RAMI 4.0 enables and standardizes the development of Health 4.0 components to send data to a cloud platform and bring information to physicians that could use it to improve the life of patients with VAD. Other case studies of RAMI 4.0 in H4.0 applications must be performed in future works to examine the hierarchy levels not used in this work and better discuss the life cycle patient-device interaction. Furthermore, the VAD connected control system and the physician platform proposed are in phase of implementation.

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