Medical systems, the role of middleware and survey on middleware design

Imad Eddine Touahria$^{1,2}$

$^1$ Department of Telematics engineering, Universidad Carlos III de Madrid, Leganes, Madrid, Spain
$^2$ Department of computer science, Ferhat Abbas Setif-1 University, Setif, Algeria

100370038@alumnos.uc3m.es imad.touahria@univ-setif.dz

Abstract. The integration of medical devices in the patient treatment process becomes increasingly important due to the efficiency of the technology. On the one hand, medical devices hardware is more powerful and its integration with the software platforms is improved. These devices are able to transfer accurate data to the clinician and offer the possibility of sharing data with other devices or computational servers for advanced analysis. On the other hand, medical software platforms are appearing to provide advanced functionality on top of these medical hardware devices. In this context, the role of the software is essential, not only at the highest abstraction level that provides the application business logic; the role of the underlying connecting software (the communication middleware or distribution software) is essential. These are capable of providing advanced connectivity functions, very efficiently, and within appropriate time bounds. This paper reviews the state of the art on middleware as facilitator for interconnection among devices and also describes a number of initiatives (such as the Integrated Clinical Environment –ICE) and projects that further extend the underlying distribution software towards the clinical domain as device interconnection facilitators.

Keywords: Medical devices · Integrated Clinical Environment · Heterogeneity · Health Data · Interoperability · Safety.

1 Introduction & motivation

By 2025 the number of patients requiring continuous monitoring will approximate 1.2 billion [63], this number shows the growing need to medical devices where continuous monitoring includes the use of devices (mobile or bedside) to improve the quality of care and safety.

The integration of technology in health care has decreased levels of mortality and has, overall, improved patient care. Health monitoring solutions are present everywhere from a small medical application deployed on a PDA (Personal Digital Assistant) to measure heart rate to complex systems deployed on a hospital server that ensures monitoring of a patient with critical or chronic diseases and clinician decision support on diagnosis. Medical devices are an example of the
new era of healthcare, as these devices offer new possibilities for physicians and a new perspective of healthcare from a data-centric and efficient interoperability (objective of this study).

The use of medical devices is essential in some critical clinical situations or when the patient is at home and needs remote diagnosis, these devices can be mobile [18, 57, 65] or installed close to the patient clinical bed [54]. The hardware/software of each device vary from others and depends on the manufacturer policy, these differences may generate some integration problems in the clinical situation. The hospital network contains a set of computational servers, switches, data recorders and medical devices/equipment; the latter ones have to be integrated in the network as Plug and Play (PuP) devices, in order to achieve this, device manufacturers have to respect standards for medical data exchange.

Improving the assistance given to patients depends greatly on the capacity of medical systems to collect large data amounts in real-time, exchange it, process it, and create new knowledge that assists medical decisions. Collecting data from multiple sensors and devices can only be done if interoperability is achieved effectively, efficiently, and in a timely manner.

Therefore, interoperability in the medical domain is an essential objective, that is not so easy to achieve given the diversity of stakeholders that vary from medical devices to computational units, to human actors. "Medical device interoperability is the ability to safely, securely, and effectively exchange and use information among one or more devices, products, technologies, or systems. This exchanged information can be used in a variety of ways including display, store, interpret, analyze, and automatically act on or control another product” [26]. OR.NET [5] and ICE [1] are examples of projects aiming to realize a safe and interoperable network of medical devices and that are studied in details in this paper.

The boost of device interconnecting has also reached e-Health, where medical devices are increasingly connected to either other devices and/or to computational servers. To support such interconnection in a safe way, medical systems actors convened on the need of a common environment to facilitate interoperability and safety. The Integrated Clinical Environment (ICE) is a new solution that includes many stakeholders where the final goal is to realize an interoperable network of medical device in a safe way [71], to achieve this medical devices manufacturers must rely to standards defined by ICE and/or other interoperability projects. Communication standards in medical devices are away to be used by manufacturers even in the same company and for devices that are from the same range, as a result, devices that have the same communication standards may not be able to communicate. According to the west health organization [6], $30 billion dollars can be saved in the USA by the adoption of functional interoperability for medical devices.

1.1 Paper structure

The paper is structured as follows. Section 2 illustrates the importance of the middleware in a distributed medical system. Section 3 describes the seminal work
Medical systems, the role of middleware and survey on middleware design

The role of the distribution software in medical systems

The lack of connectivity among medical devices is caused by differences in operating systems, networking ports, data formatting and encoding. Many important projects are trying to realize an effective integration of these devices in the clinical room and achieve an interoperable and secure solutions. These are all lower levels of technicalities that typically are taken care of by the distribution software. The most widely adopted standards such as ICE need to build on top of efficient solutions such as DDS [62].

However, there is a long way on design of the middleware for efficient communications across nodes to provide interoperability, timeliness, flexibility, reconfiguration, and many other characteristics.

In this paper, a study of a selected set of middleware research works have been analyzed, mostly those related to the research on distributed real-time systems group that are the background to the research on this field introduced there. This broad work goes from resource management techniques for operating systems (that are essential to middleware), middleware design, service oriented middleware, real-time reconfiguration, and hardware accelerated execution of middleware. Now, this work is being extended to target medical systems. Therefore, to complement this survey, a further description of higher abstraction solutions for the medical domain is given and also the applications of the previous work to specific medical scenarios.

3 Background on distribution sofware design

This section presents a selected set of works related to the design of real-time middleware and resource management. These contributions are essential to achieve efficient communication and distribution infrastructures that support efficiently the interoperation of distributed medical devices.

Cyber-physical systems. Medical devices are integrated as part of cyber-physical systems (CPS) that monitor the physical conditions of systems and actuate on them or help in deciding how a human physician will actuate on the patients. Because they are cyber-physical systems, they require rigorous design techniques that tend to be based on formal methods supporting the verification of their properties.

The evolution and flexible nature of a CPS in the context of medical systems is justified by the fact that they are related to human monitoring and this is
a quite unstable situation that can raise different unexpected events. For this reason, supporting evolution and flexibility are among the greatest challenges to be tackled. Reconciling the uncertainty derived from the unknown monitored conditions of a patient, etc., and the need to react in real-time is extremely hard to integrate all together as all the possible situations that can be encountered at run time can not be known a priori. In [47], a formal design is described based on Petri nets to model systems that can evolve; this technique was also explored in [46]. A different formal method approach is applied in [17] and [16].

In the above works, the focus is placed on the design of the software component interactions relative to their timing properties and other behavioral parameters that are modeled. However, the communication across the above components is a key aspect that must be analyzed to achieve communication and interaction infrastructures that support timely interaction and variable conditions such as load peaks or coexistence of components with heterogeneous resource usage patterns. For this purpose, there are also a number of contributions for the design of distribution middleware for CPS as middleware is the key software layer that is capable of abstracting distribution and interaction, masking situations where a node can receive a peak of requests from other nodes; the systems must be resilient to these and other situations, and they have to continue to work at all times. The design of adaptive middleware is provided in OmaCy architecture [33]. In [34] and [38], an analysis of this problem is outlined. In [36], the design of a scheme for attending simultaneous requests is provided. In [32], a model for integrating the Data Distribution Software with single board computers and Raspberry Pi is provided; this is further reworked in [40] for a different domain such as avionics. Also, there have been a number of dedicated research contributions to building real-time facilities in middleware such as [38, 39, 49], among others; or building abstractions for utilization of multiple interaction paradigms such as [66] or [43].

Medical systems. The role of middleware in medical systems is key to achieve safe execution and timely operation that can, in the end, save lives. Well proven service-oriented architectures such as iLAND [44] have been integrated with ICE in [48]. The reconfiguration capabilities [29] and timely communication capacities of iLAND have been proposed to be the core interoperation backbone for ICE. A number of studies for profiling the actual performance of communication middleware such as [41] has been particularized for medical systems in a number of works such as [42] for the Internet Communications Engine and [67] for AMQP. Moreover, a number of improvements to their execution by making the middleware aware of the underlying hardware structure have been undertaken in [35] and the benefits of this acceleration in medical systems for remote patient monitoring has been exemplified in [37].

Resource management and components for real-time. This section continues to move down the abstraction level in the way towards designing flexible cyber-physical systems focusing at the middleware view.
The basics of the middleware design is the control of the execution at thread or task level. There are a number of contributions on the architecting of real-time middleware from a real-time perspective such as the following such as Hola-QoS [31]; using real-time scheduling for distributed actions [13]; real-time quality of service management [64]; mode changing policies for timely execution [7,30]; agents modeling real-time properties [19]; identification of Linux kernel properties for improving locking [20]; architecting open source projects for Linux [21]; analysis of temporal behavior at bus level within a multiprocessor [51]; reconfiguration scheduling [45].

Other contributions for service oriented systems have been [14]; or component-based modeling over QoS networking [22]; have progressively shed light over how to handle execution in systems using more abstract modeling like encapsulation through services and separating application from networking responsibilities.

4 Medical devices and medical communication standards

The world health organization defines a medical device [7] as: “Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: 1. Diagnosis, prevention, monitoring, treatment or alleviation of disease. 2. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury. 3. Investigation, replacement, modification, or support of the anatomy or of a physiological process. 4. Supporting or sustaining life. 5. Control of conception. 6. Disinfection of medical devices. 7. Providing information by means of in vitro examination of specimens derived from the human body. ”

As shown in figure 1 and according to the previous definitions, a wide variety of devices can be considered as a medical device. Medical devices that have software/hardware components, measure patient vital signs, have network or data sharing ports and are even mobile or bedside are included in this study.

![Example of medical devices](image_url)
4.1 Software and hardware characteristics of medical devices

The strict regulations on design and development of medical systems are a challenge. FDA (Food and Drug Administration) is considered as the most important organization that establishes regulations for medical devices development. There have been some critics on its role in minimizing innovation, e.g., X-Ray machines innovation caused by strict FDA strict regulations. The European Union adopted the MDD (Medical Device Directive) that is a set of standards and regulations that manufacturers of medical devices must respect in order to set up there devices.

Among these regulations there are: the Medical Device Directive (MDD 93/42/EEC), the In Vitro Diagnostic Medical Device Directive (IVMD98/79/EC) and the Active Implantable Medical Device Directive (AIMDD 90/385/EEC) despite these different regulation development, the countries involved most in medical device regulation established the Global Harmonization Task Force (GHTF) and, after that, the International Medical Device Regulators Forum (IMDRF) appeared, it objective is to accelerate international medical device regulatory harmonization and convergence with respect to safety, performance and quality of medical devices.

According to WHO (World Health Organization) definition, a medical device can be a software, and IMDRF defined the concept of “Software as a Medical Device” that is a software intended to be used for one or more medical functions that perform them without being part of a hardware medical device. But, according to the view of this study on medical devices, a software is a medical device when the functional properties of the software are enough to handle the situation where the software is used as a medical device.

Software is progressively playing an increasingly important role in healthcare, and consequently, so is the role of the middleware that it contains. A medical device software has safety requirements, and, therefore, it must operate adhering strictly to parameters of accuracy, high integrity, security, and should be verified and validated through software development methodologies. This is in line with the requirements of cyber-physical systems.

The main objective to fix when developing medical device software is safety, in order to achieve safety, the software of medical devices has to comply to standards like: European MDD, ISO 13485, IEC 62366, ISO 14971 and others.

The hardware characteristics of medical devices vary from a manufacturer to another. The weight, size, ports, network connections, displays, mobile/bedside and cable connections can vary depending on the use of the device and the clinical situation where it is deployed; so that different models for a single manufacturer are also common. Even the materials used to construct the medical devices must be analyzed to avoid electrical shocks or allergy of the patients. This study concentrates on input/output ports and network connections of the device.

In order to communicate medical devices, these are provided with input/output ports, data output ports vary across suppliers of medical devices. The most common ports are RS 232 port (DB-9, DB-15, and DB-25), RJ 45, wireless LAN,
Medical systems, the role of middleware and survey on middleware design

Bluetooth, USB, or some proprietary data connection systems developed by suppliers for using data by their own IT systems. The following are the most common hardware connections used by suppliers to input data into the device: PS/2 (for supporting keyboard or a mouse inputs), USB, RS 232, and digital data input [71]. Figure 2 shows how medical devices are integrated in a clinical situation and the way how medical devices are connected to the patient body, to each other and to networking devices.

![Operating room](image)

Fig. 2. Example of medical devices use in a clinical situation

4.2 Networking and messaging.

Communication and data exchange between medical devices is a part of interoperability. Data and communication exchange between medical devices is characterized by a set of standards that are detailed in what follows.

**DICOM** (Digital Imaging and Communications in Medicine) is a standard developed by the National Electrical Manufacturers Association (NEMA) to store retrieve and transfer medical imaging from various medical devices such as scanners, printers, network hardware etc [23]. DICOM promotes digital information exchange between medical imaging equipment and other systems, and therefore medical imaging is done between physicians or medical centers in an interoperable way.

**HL7 version 2** is a standard of data exchange in healthcare, designed to support data messaging in a centralized or distributed environment and propose interfaces communication to stakeholders that do not adhere to data exchange standards. 95% of hospitals, 95% of medical related equipment and information systems in the whole America use HL7 standard; also, it is used in Germany, Japan and other developed countries [58].
HL7 version 3 is a newer version of HL7 version 2 that uses the eXtensible Markup Language (XML) as a powerful tool in the web to transfer data. Also, version 3 integrates web services and the Web Services Description Language (WSDL) [61]. Version 3 of HL7 promotes semantic interoperability defined a more explicit methodology for the development of messages [68].

4.3 Interoperability.

Integrated in the same clinical situation, medical devices must communicate in order to provide high quality healthcare. Interoperability is the basis of data exchange in the clinical environment. When connected to a PC, the printer doesn’t need to be programmed to be able to communicate with the PC, interoperability between medical devices is expected to achieve that level.

HL7. The main objective of HL7 is to achieve an interoperable network of medical devices in a secure way. For this, it deals with data and the way it is transferred between devices and HIS (Health Information Systems). Also, other technologies cited above can be classified under more than one section.

ISO/IEEE 11073 is a family of standards for plug and play interoperability of medical devices, defines a common framework for the establishment of a unified data structure model [56]. ISO/IEEE 11073 (X73PHD) [3, 70] objective is to standardize Personal Health Devices (PHDs) and allow semantic interoperability of medical devices by defining the structure of data and the protocol for information delivery between individual medical devices (Glucose meter, Weight scale, Blood pressure monitor, etc.) and the manager (computer, smartphone, set top box, etc.), which collects and manages the information from the individual medical devices [60].

FHIR (Fast Healthcare Interoperability Resources) of HL7 is the most recent standard of the series of standards (HL7 v2, HL7 v3, CDA) developed by HL7 [15], it is a framework for the exchange of electronic health records (EHR) data that combines the evolving modern technologies and market needs [52]. FHIR aims to follow the Representational State Transfer (REST) architectural style as presented by Fielding [25] and presents the stakeholders from the healthcare as resources: medical devices, clinicians, medications, IT structures, etc.

DPWS (Devices Profile for Web Services) uses SOA (Service Oriented Architecture) for providing interoperable, cross-platform, cross-domain, and network-agnostic access to devices and their services [28]. DPWS is used for embedded devices with limited resources by enabling Web services using IoT applications. DPWS requires WSDL (Web Service Description Language) and SOAP (Simple Object Access Protocol) to communicate the device services, but it does not need a registry like UDDI (Universal Description, Discovery and Integration) for services discovery. DPWS aims to achieve interoperability by using the loosely coupled concept of Web services over the MD operation and data encryption.

MDPWS (Medical Devices Profile for Web Services) is a part of IEEE 11073-20702 series of standards and uses the principles of DPWS but for medical devices interoperability domain with some modifications like the restricted security mechanisms of MDPWS comparing with DPWS, e.g. the usage of client au-
thentication with HTTP authentication is withdrawn in favor of using X.509.v3 certificates \[53\]. MDPWS uses the principles of DPWS with respect to the high acuity patient environment and the complexity of medical devices.

4.4 Coordination frameworks

ICE (Integrated Clinical Environment) \[1\] architecture was defined in 2009 in ASTM (American Society for Testing and Materials) F2761 standard. ICE aims to cover the heterogeneity of medical devices by implementing a plug and play environment of medical devices and creating a communication gateway between them, where messages and commands are exchanged successfully. Suppliers of medical devices must adjust the set of specifications provided by ICE in order to create devices that are ICE-compliant: medical devices must have a network output port and must produce data that can be managed through ICE interfaces. ICE aims to:

- Improve patient safety by coordinating medical devices actions and avoid incorrect medical decisions generated by a faulty device operation.
- Ensure support for clinicians in their monitoring and treatment operation, where clinical aid information is generated by a set of workflows implemented in the ICE framework logic.
- Create a flexible communication bus between medical devices, servers running medical applications, and the clinicians.
- Implement an interoperable network of medical devices and computational servers where data and messages are exchanged in real time.
- Define standards for the hardware and software characteristics or dimensions of medical devices that will be used by manufacturers to produce medical devices that comply with ICE.

In ICE-based systems safety is the ability to implement interoperability between heterogeneous medical devices in a single high acuity patient environment where communication is done via software or hardware interfaces. ICE aims to improve patient safety by elaborating and deploying interoperability of the medical devices, thus, creating an interoperable communication bus between heterogeneous medical devices where messages and commands are exchanged. ICE defines the following objectives in order to underline and improve patient safety:

- Encapsulates errors generated by medical devices that affect patient safety. Errors can be wrong values for a given vital sign or a false alarm.
- Records errors in order to achieve a system that can predict a given behavior when the system faces pre-saved errors.
- Creates a support workflow for clinicians to notify them if the patient health status is deteriorating.
- Introduces a risk management process and defines risk levels that are directly related to the policy of the manufacturer.
• Defines the concept of basic safety as the elimination of medical risks directly related with the physical hazards when a medical device is used in normal conditions. Safety is a wider definition of basic safety.
• Supports alarms generated by medical devices. Each alarm is provided to the clinician with its cause and time of generation.

**OR.NET.** OR.NET is a solution developed by German academics and industrials for medical devices integration and medical systems interoperability in the operating room and its surroundings. The objective of OR.NET is to develop basic concepts for the secure dynamic networking of computer-controlled medical devices in the operating room and clinic. In the end, these concepts are evaluated and transformed to standards. OR.NET aims to create a service-oriented architecture for the safe and secure dynamic interconnection of medical devices in the OR context. OR.NET project aims to:

• Develop standards for dynamic integration of medical devices in the OR and beyond.
• Solve the problem of the approval of modular devices in an open networked OR system.
• Define risk management and usability analysis processes via open interfaces in all the OR system.
• Achieve hard real time communication between the medical devices using SRTB (Surgical Real Time Bus).
• Define an architecture that has security and privacy as first class citizens in order to protect data and patient safety.
• User interface profiles analysis including GUI interaction elements and input/output ports to develop reliable and usable medical devices.
• Adhere to use IEEE 11073 family standards including 20701, 20702 and 10207.

Furthermore, requirements were identified for test scenarios to verify that the devices safely communicate with each other. This includes the validation of the standard conformity of the messages being transferred and of the way the systems behave on receiving regular messages or also in various exceptional situations, such as network problems, dealing with faulty data, or how to react when unauthorized users try to take over control.

OR.NET also allows the use of different communication protocols (e.g. DICOM and HL7 Version 2). OSCP explicitly does not try to replace these widespread protocols. Instead, dedicated gateways are specified that enable the operation of the DICOM and HL7 protocols despite the separation of OR network and the hospital network.

5 Conclusion and future works

This paper has summarized the importance of distribution and communication middleware inside distributed medical systems that are composed of medical devices that can be highly interconnected. The interaction across the elements of
a distributed medical system is as efficient as the underlying middleware software that supports its interoperation, coordination, and communication. For this purpose, there are a number of contributions at the levels of entity (component, service, etc.) definition, entity interoperability, and resource management that are relevant in this context. This paper has given value to the work of the distributed real-time systems lab in this domain as a baseline for building efficient middleware specifically tailored to distributed medical systems.

References

1. CIMIT - Center for Integration of Medicine and Innovative Technology. [http://www.cimit.org/](http://www.cimit.org/) Accessed: 2018-07-02.
2. FDA - US Food and Drug Administration. [https://www.fda.gov/](https://www.fda.gov/) Accessed: 2018-07-13.
3. IEEE 11073 Personal health devices. [http://www.11073.org/](http://www.11073.org/) Accessed: 2018-08-16.
4. International Medical Device Regulators Forum. [http://www.imdrf.org/](http://www.imdrf.org/) Accessed: 2018-07-13.
5. OR.NET - Operating Room project. [http://ornet.org/](http://ornet.org/) Accessed: 2018-07-01.
6. West health organization. [http://www.who.int/en/](http://www.who.int/en/) Accessed: 2018-07-12.
7. World Health Organization - Medical Device Full Definition. [http://www.who.int/medical-devices/full-definition/en/](http://www.who.int/medical-devices/full-definition/en/) Accessed: 2018-07-12.
8. European Council - Council Directive 1993/42/EC. ed.Luxembourg: Official Journal of the European Union, 1993.
9. European Council - Council Directive 2007/47/EC. ed.Luxembourg: Official Journal of the European Union, 2007.
10. International Electrotechnical Commission - IEC 62366:2007. Medical devices - Application of usability engineering to medical devices, ed. Geneva., 2007.
11. International Organization of Standardization - ISO 13485:2012. Medical devices - Application of risk management to medical devices, ed. Geneva, 2012.
12. International Organization of Standardization - ISO 13485:2012 Medical Devices, Quality management system. Requirements fo regulatory purposes, ed. Geneva, 2012.
13. Alejandro Alonso, Marisol García-Valls, and Juan Antonio de la Puente. Assessment of timing properties of family products. In Development and Evolution of Software Architectures for Product Families, Second International ESPRIT ARES Workshop, Las Palmas de Gran Canaria, Spain, February 26-27, 1998, Proceedings, pages 161–169, 1998.
14. Gaetano F. Anastasi, Tommaso Cucinotta, Giuseppe Lipari, and Marisol García-Valls. A qos registry for adaptive real-time service-oriented applications. In 2011 IEEE International Conference on Service-Oriented Computing and Applications, SOCA 2011, Irvine, CA, USA, December 12-14, 2011, pages 1–8, 2011.
15. D. Bender and K. Sartipi. Hi7 fir: An agile and restful approach to healthcare information exchange. In Proceedings of the 26th IEEE International Symposium on Computer-Based Medical Systems, pages 326–331, June 2013.
16. Marcello M. Bersani and Marisol García-Valls. The cost of formal verification in adaptive CPS, an example of a virtualized server node. In 17th IEEE International Symposium on High Assurance Systems Engineering, HASE 2016, Orlando, FL, USA, January 7-9, 2016, pages 39–46, 2016.
17. Marcello M. Bersani and Marisol García-Valls. Online verification in cyber-physical systems: Practical bounds for meaningful temporal costs. *Journal of Software: Evolution and Process*, 30(3), 2018.

18. A. Bestbier and P. R. Fourie. Development of a vital signs monitoring wireless ear probe. In *2018 3rd Biennial South African Biomedical Engineering Conference (SAIBMEC)*, pages 1–5, April 2018.

19. Alberto Montilla Bravo and Marisol García-Valls. Fipa-based qos negotiator for nomadic agents. In *Mobile Agents for Telecommunication Applications, 4th International Workshop, MATA 2002 Barcelona, Spain, October 23–24, 2002, Proceedings*, pages 216–226, 2002.

20. Peter T. Breuer and Marisol García-Valls. Static deadlock detection in the linux kernel. In *Reliable Software Technologies - Ada-Europe 2004, 9th Ada-Europe International Conference on Reliable Software Technologies, Palma de Mallorca, Spain, June 14-18, 2004, Proceedings*, pages 52–64, 2004.

21. Peter T. Breuer and Marisol García-Valls. Raiding the noosphere: the open development of networked RAID support for the linux kernel. *Softw., Pract. Exper.*, 36(4):365–395, 2006.

22. M. A. de Miguel, J. F. Ruiz, and M. Garcia. Qos-aware component frameworks. In *IEEE 2002 Tenth IEEE International Workshop on Quality of Service (Cat. No.02EX564)*, pages 161–169, May 2002.

23. A. J. Dinu, R. Ganesan, A. A. Kebede, and B. Veerasamy. Performance analysis and comparison of medical image compression techniques. In *2016 International Conference on Control, Instrumentation, Communication and Computational Technologies (ICICICT)*, pages 738–745, Dec 2016.

24. Karen B Ekelman et al. Technological innovation and medical devices. 1988.

25. Roy Thomas Fielding. *Architectural Styles and the Design of Network-based Software Architectures*. PhD thesis, 2000. AAI9980887.

26. Food and Drug Administration. Medical Device Interoperability. [https://www.fda.gov/MedicalDevices/DigitalHealth/ucm512245.htm](https://www.fda.gov/MedicalDevices/DigitalHealth/ucm512245.htm). Accessed: 2018-07-01.

27. Elaine French-Mowat and Joanne Burnett. How are medical devices regulated in the european union? *Journal of the Royal Society of Medicine*, 105(1_suppl):22–28, 2012.

28. K. Fysarakis, D. Mylonakis, C. Manifavas, and I. Papaeftathiou. Node.dpws: Efficient web services for the internet of things. *IEEE Software*, 33(3):60–67, May 2016.

29. Marisol García-Valls. A proposal for cost-effective server usage in CPS in the presence of dynamic client requests. In *19th IEEE International Symposium on Real-Time Distributed Computing, ISORC 2016, York, United Kingdom, May 17-20, 2016*, pages 19–26, 2016.

30. Marisol García-Valls, Alejandro Alonso, and Juan Antonio de la Puente. Mode change protocols for predictable contract-based resource management in embedded multimedia systems. In *International Conference on Embedded Software and Systems, ICESS ’09, Hangzhou, Zhejiang, P. R. China, May 25-27, 2009.*, pages 221–230, 2009.

31. Marisol García-Valls, Alejandro Alonso, José Ruiz, and Angel Groba. *An Architecture of a Quality of Service Resource Manager Middleware for Flexible Embedded Multimedia Systems*, pages 36–55. Springer Berlin Heidelberg, Berlin, Heidelberg, 2003.

32. Marisol García-Valls, Javier Ampuero-Calleja, and Luis Lino Ferreira. Integration of data distribution service and raspberry pi. In *Green, Pervasive, and Cloud*
33. Marisol García-Valls and Roberto Baldoni. Adaptive middleware design for CPS: considerations on the os, resource managers, and the network run-time. In Proceedings of the 14th International Workshop on Adaptive and Reflective Middleware, ARM@Middleware 2015, Vancouver, BC, Canada, December 7-11, 2015, pages 3:1–3:6, 2015.

34. Marisol García-Valls, Paolo Bellavista, and Aniruddha S. Gokhale. Reliable software technologies and communication middleware: A perspective and evolution directions for cyber-physical system, mobility, and cloud computing. Future Generation Comp. Syst., 71:171–176, 2017.

35. Marisol García-Valls and Christian Calva-Urrego. Improving service time with a multicore aware middleware. In Proceedings of the Symposium on Applied Computing, SAC 2017, Marrakech, Morocco, April 3-7, 2017, pages 1548–1553, 2017.

36. Marisol García-Valls, Christian Calva-Urrego, Juan Antonio de la Puente, and Alejandro Alonso. Adjusting middleware knobs to assess scalability limits of distributed cyber-physical systems. Computer Standards & Interfaces, 51:95–103, 2017.

37. Marisol García-Valls, Christian Calva-Urrego, and Ana García-Fornes. Accelerating smart eHealth services execution at the fog computing infrastructure. Future Generation Comp. Syst., –:–, 2018.

38. Marisol García-Valls, Antonio Casimiro, and Hans P. Reiser. A few open problems and solutions for software technologies for dependable distributed systems. Journal of Systems Architecture - Embedded Systems Design, 73:1–5, 2017.

39. Marisol García-Valls and Tommaso Cucinotta. Real-time and distributed computing in emerging applications. foreword by the general chairs of reaction 2012. Journal of Systems Architecture - Embedded Systems Design, 61(5-6):267–268, 2015.

40. Marisol García-Valls, Jorge Domínguez-Poblete, Imad Eddine Touahria, and Chenyang Lu. Integration of data distribution service and distributed partitioned systems. Journal of Systems Architecture - Embedded Systems Design, 83:23–31, 2018.

41. Marisol García-Valls, Daniel Garrido, and Manuel Díaz. Impact of middleware design on the communication performance. In Green, Pervasive, and Cloud Computing - 12th International Conference, GPC 2017, Cetara, Italy, May 11-14, 2017, Proceedings, pages 505–519, 2017.

42. Marisol García-Valls, Natividad Herrasti, Christophe Jouvray, and Aintzane Armendariz. Flexible and timely on-line integration of medical services using iland middleware. SIGBED Review, 14(2):53–60, 2017.

43. Marisol García-Valls and Felipe Ibáñez-Vázquez. Integrating middleware for timely reconfiguration of distributed soft real-time systems with ada DSA. In Reliable Software Technologies - Ada-Europe 2012 - 17th Ada-Europe International Conference on Reliable Software Technologies, Stockholm, Sweden, June 11-15, 2012. Proceedings, pages 35–48, 2012.

44. Marisol García-Valls, Iago Rodríguez Lopez, and Laura Fernández-Villar. iland: An enhanced middleware for real-time reconfiguration of service oriented distributed real-time systems. IEEE Trans. Industrial Informatics, 9(1):228–236, 2013.

45. Marisol García-Valls, Alejandro Alonso Muñoz, and Juan Antonio de la Puente. Time-predictable reconfiguration with contract-based resource management. In 23rd International Conference on Advanced Information Networking and Applications, AINA 2009, Workshops Proceedings, Bradford, United Kingdom, May 26-29, 2009, pages 494–499, 2009.
46. Marisol García-Valls, Diego Perez-Palacin, and Raffaela Mirandola. Time-sensitive adaptation in CPS through run-time configuration generation and verification. In IEEE 38th Annual Computer Software and Applications Conference, COMPSAC 2014, Vasteras, Sweden, July 21-25, 2014, pages 332–337, 2014.

47. Marisol García-Valls, Diego Perez-Palacin, and Raffaela Mirandola. Pragmatic cyber physical systems design based on parametric models. Journal of Systems and Software, 144:559–572, 2018.

48. Marisol García-Valls and Imad Eddine Touahria. On line service composition in the integrated clinical environment for ehealth and medical systems. Sensors, 17(6):1333, 2017.

49. Marisol García-Valls and Antnio Casimiro, and Hans P. Reiser. A few open problems and solutions for software technologies for dependable distributed systems. Journal of Systems Architecture, 73:1 – 5, 2017. Special Issue on Reliable Software Technologies for Dependable Distributed Systems.

50. Julian M Goldman. Medical devices and medical systems essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE)-Part 1: General requirements and conceptual model. ASTM International, 2008.

51. Angel M. Groba, Alejandro Alonso, José A. Rodríguez, and Marisol García-Valls. Response time of streaming chains: Analysis and results. In 14th Euromicro Conference on Real-Time Systems (ECRTS 2002), 19-21 June 2002, Vienna, Austria, Proceedings, page 182, 2002.

52. N. Hong, K. Wang, L. Yao, and G. Jiang. Visual fhir: An interactive browser to navigate hl7 fhir specification. In 2017 IEEE International Conference on Healthcare Informatics (ICHI), pages 26–30, Aug 2017.

53. M. Kasparick, S. Schlichting, F. Golatowski, and D. Timmermann. Medical dpws: New ieee 11073 standard for safe and interoperable medical device communication. In 2015 IEEE Conference on Standards for Communications and Networking (CSCN), pages 212–217, Oct 2015.

54. A. King, S. Procter, D. Andresen, J. Hatchiff, S. Warren, W. Spees, R. Jetley, P. Jones, and S. Weininger. An open test bed for medical device integration and coordination. In 2009 31st International Conference on Software Engineering - Companion Volume, pages 141–151, May 2009.

55. M. Lepmets, T. McBride, and F. McCaffery. Towards safer medical device software systems: Industry-wide learning from failures and the use of safety-cases to support process compliance. In 2016 10th International Conference on the Quality of Information and Communications Technology (QUATIC), pages 193–198, Sept 2016.

56. Hai-Long Li, Zhi-Bin Duan, Jin-Zhong Cui, and Zhen-Wei Chen. A design of general medical data adapter based on iso/ieee 11073 standards. In 2015 12th International Computer Conference on Wavelet Active Media Technology and Information Processing (ICCWAMTIP), pages 404–407, Dec 2015.

57. J. Lu, W. Hu, M. Song, X. Zhan, and X. Liu. Mobile medical service system based on portable devices. In 2015 IEEE 17th International Conference on High Performance Computing and Communications, 2015 IEEE 7th International Symposium on Cyberspace Safety and Security, and 2015 IEEE 12th International Conference on Embedded Software and Systems, pages 1530–1535, Aug 2015.

58. X. Lu, Y. Gu, J. Zhao, N. Yu, and W. Jia. Research and implementation of medical information format conversion based on hl7 version 2.x. In 2011 International Conference on Computer Science and Service System (CSSS), pages 2440–2443, June 2011.
59. M. Mchugh, F. Mccaffery, and V. Casey. Software process improvement to assist medical device software development organisations to comply with the amendments to the medical device directive. *IET Software*, 6(5):431–437, October 2012.

60. J. Nam, W. Seo, J. Bae, and Y. Cho. Design and development of a u-health system based on the iso/ieee 11073 phd standards. In *The 17th Asia Pacific Conference on Communications*, pages 789–793, Oct 2011.

61. R. Noumeir and J. F. Pambrun. Hands-on approach for teaching hl7 version 3. In *Proceedings of the 10th IEEE International Conference on Information Technology and Applications in Biomedicine*, pages 1–4, Nov 2010.

62. OMG. Data distribution software, v1.4. https://www.omg.org/spec/DDS/, 2015.

63. World Health Organization. *Diet, nutrition, and the prevention of chronic diseases: report of a joint WHO/FAO expert consultation*, volume 916. World Health Organization, 2003.

64. Clara Otero-Pérez, Liesbeth Steffens, Peter van der Stock, Sjir van Loo, Alejandro Alonso, José Ruiz, Reinier Brill, and Marisol García-Valls. Qos-based resource management for ambient intelligence. 2003.

65. V. Randazzo, E. Pasero, and S. Navaretti. Vital-ecg: A portable wearable hospital. In *2018 IEEE Sensors Applications Symposium (SAS)*, pages 1–6, March 2018.

66. Iago Rodríguez-López and Marisol García-Valls. Architecting a common bridge abstraction over different middleware paradigms. In *Reliable Software Technologies - Ada-Europe 2011 - 16th Ada-Europe International Conference on Reliable Software Technologies, Edinburgh, UK, June 20-24, 2011. Proceedings*, pages 132–146, 2011.

67. Paloma Rubio-Conde, Diego Villarán-Molina, and Marisol García-Valls. Measuring performance of middleware technologies for medical systems: Ice vs AMQP. *SIGBED Review*, 14(2):8–14, 2017.

68. M. I. Sabar, P. M. Jayaweera, and E. A. T. A. Edirisuriya. International interoperability through unified universal hl7 v3 green messaging. In *2015 Fifteenth International Conference on Advances in ICT for Emerging Regions (ICTer)*, pages 112–118, Aug 2015.

69. J. Schlamelcher, M. Onken, M. Eichelberg, and A. Hein. Dynamic dicom configuration in a service-oriented medical device architecture. In *2015 37th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC)*, pages 1717–1720, Aug 2015.

70. ISO Staff. Iso/ieee 11073-20601: Health informatics–personal health device communication; part 20601 application profile-optimized exchange protocol. *Ginebra, Suiza*, 2010.

71. I. E. Touahria, M. García-Valls, and A. Khababa. An ice compliant component model for medical systems development. In *2017 IEEE 41st Annual Computer Software and Applications Conference (COMPSAC)*, volume 1, pages 278–287, July 2017.