Process-Oriented Analysis for Medical Devices

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Abstract

Medical Cyber Physical Systems are widely used in modern healthcare environments. Such systems are considered life-critical due to the severity of consequences that faults may cause. Effective methods, techniques and tools for modeling and analyzing medical critical systems are of major importance for ensuring system reliability and patient safety.

This work is looking at issues concerning different types of medical industry needs including safety analysis, testing, conformance checking, performance analysis and optimization. We explore the possibility of addressing these issues by exploiting information recorded in logs generated by medical devices during execution. Process-oriented analysis of logs is known as process mining, a novel field that has gained considerable interest in several contexts in the last decade.

Process mining techniques will be applied to an industrial use case provided by Fresenius, a manufacturer of medical devices, for analyzing process logs generated by an infusion pump.

1998 ACM Subject Classification B.3.3 Performance Analysis and Design Aids, B.5.3 Reliability and Testing, D.2.2 Design Tools and Techniques, I.2.6 Learning, I.5 Pattern Recognition

Keywords and phrases Process Logs, Process Mining, Discovery, Formal Analysis, Infusion Pump

Digital Object Identifier 10.4230/OASIcs.MCPS.2014.143

1 Introduction

Medical Cyber physical systems couple tightly the cyber and physical parts to provide mission-critical services in clinical environments [6]. They can be found embedded in a wide range of medical devices from small size, including infusion pumps and pacemakers, to large equipment such as x-rays. Medical devices are widely used in modern healthcare environments improving effectiveness of the patient care. Nevertheless, medical devices enormous complexity may affect the quality and the reliability of the overall system, putting patients at risk.

Much consideration is being given to rigorous system design and analysis methods for improving the trustworthiness of medical devices and verifying safety properties. Ensuring safety and reliability has been studied for various medical devices including the pacemaker [5] and the PCA Infusion Pump [11]. In the latter case, model-driven engineering is proposed for establishing a safety assured implementation. The generic PCA reference model is translated from Simulink to Timed Automata and its safety requirements described in temporal logic formulae. Using the UPPAAL tool [4], requirements are verified for satisfiability.

In the medical devices industry, design tools such as Matlab/Simulink and Unified Modeling Language(UML) are used for modeling the embedded system. However, in spite of several contributions on defining semi-formal semantics for those specifications, they are still not considered formal languages. Formal analysis need to be conducted on unambiguous specification, thus transforming the underlying specification into a formal model is imperative. Depending on the complexity of the system, model transformation can be a time consuming, tedious and error-prone task.

This work proposes an alternative approach of analyzing and ensuring safety properties of medical devices. Based on the process logs generated from the execution of a device, it is possible to extract process related information e.g. process model or reconstruct the system model in a formal representation. This methodology also known as process mining [8], offers a wide range of analysis that can be performed on the generated model. It does not only provide the means to increase safety and reliability of a system, it also opens up new possibilities of performance analysis and optimization.

These aposteriori formal reasoning can complement existing analysis performed at the model at design level such as model checking. Extracting a formal model from generated logs, for already designed and implemented systems, may accelerate the desired analysis and be more time efficient.

The remainder of this paper, presents the basic idea of process mining and the benefits of applying process mining techniques for analyzing medical devices.

2 Process Mining

Process Mining [1] is a model-driven approach aiming at constructing process models based on available process logs stored by information systems. A process model is a formal representation of a process. It may represent several process information, like activity executions, actors, roles, resources, time, data, among others. Starting from a process log that represents the footprints left by executing a process, process mining techniques may derive a formal process model that represents the underlying process. For instance, a process model may focus on the control-flow perspective, i.e., the order of execution of activities within a process execution. Process models can be described in different process modeling languages such as BPMN, Petri Nets or Event Driven Process Chain.

A fundamental goal of process mining is the discovery and extraction of the model that describes the process underlying in the process log. The reconstruction of the model is the aim itself but process mining it is not limited to that. Conformance checking can be performed to compare the derived model with the process log and monitor possible deviations. Notice that while in discovery the only algorithm's input is the log, in conformance two inputs are considered: the log and the process model, the latter can be either obtained by a discovery technique or manually designed from an expert. Analysis might aim also at additional objectives including optimization of the process, testing for satisfiability of safety properties, performance analysis etc.

In contrast to data mining, process mining techniques focus on the process perspective, and hence the causal relations between different events of a process are identified. Process mining is applicable to systems (e.g. ERP systems or embedded systems) that record their behavior and produce process logs. Current research of process mining in the health-care domain is in early stages. In [9], process mining was used to obtain insights related to careflows for gynecological oncology patients. In [2] datasets of stroke patients have been analyzed to demonstrate how to construct models for a whole data set or for only aspects

Trace ID	Activity
0	init
	trans(N)
	turn
	mMStart
	stop
	Dconnect
	mMStop
	trans(I)
	trans(F)
1	init
	trans(N)
	turn
	trans(I)
	trans(F)
2	init
	trans(N)
	trans(I)
	trans(F)
...	...

(a)

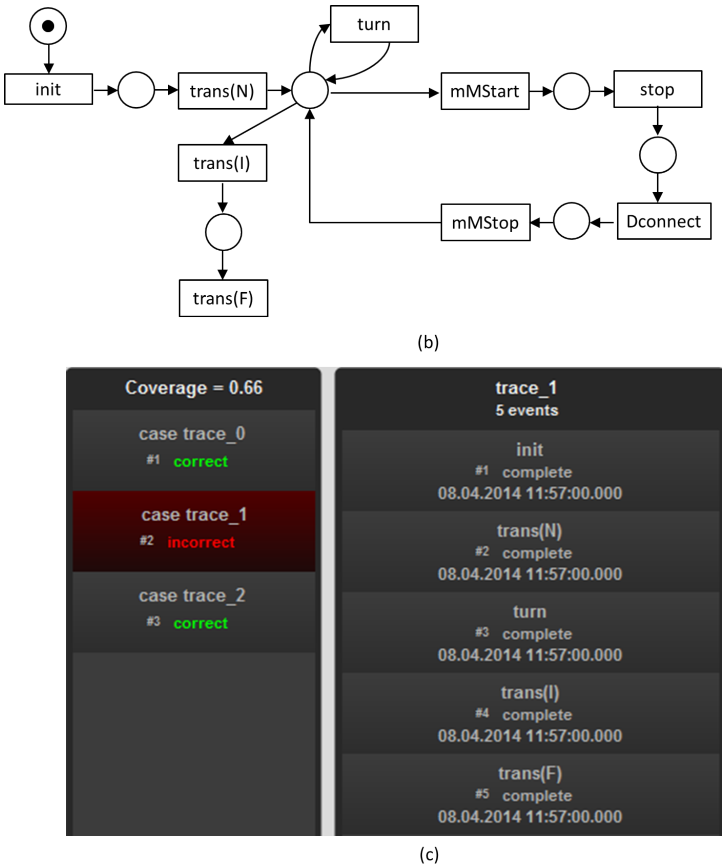

Figure 1 (a) Generated traces from an Infusion Pump, (b) Discovered Model, (c) Verifying property.

that are of interest for identifying for instance differences in treatment strategies between different hospitals. Finally, the work [3] presents a framework to support process mining in critical care that enables improvement for clinical guideline.

However, process mining in health care has not yet been considered within the context of medical devices and towards the analysis of embedded software. In this context, process mining techniques can be exploited for performing formal analysis and focusing on other aspects such as performance and optimization.

To give an impression of how process mining could be applied to the analysis of medical software, an example is illustrated in Figure 1. Figure 1(a) shows hypothetical logs generated by the execution of an infusion pump software. Several activities are performed at each trace 0, 1 and 2. The Petri Net in Figure 1(b) is discovered using the ILP algorithm of ProM tool [12]. ProM is a platform independent open source framework which supports a wide variety of data and process mining techniques in form of plug-ins. Using the LTL checker plug-in, the property *always_when_turn_then_eventually_stop* is verified. Figure 1(c) indicates the trace that violates the given property. This is due to the fact that action turn is not followed by stop.

3 Conclusions

We presented Process Mining, an approach for performing analysis using event logs generated by medical devices. Using process mining techniques, we can exploit the information recorded in the event logs.

We explore the possibility of conducting log-based verification [10] in order to prove satisfiability of safety properties. Applying log-based verification to already designed systems could be a faster way than model checking to prove properties. Manufacturers, such as Fresenius [7], could be particularly interested by such an approach. The main reason is that analysis can be performed without the effort of transforming existing models into the formal description compatible with a model checker.

However, there are many challenges associated with the approach of log-based verification. What are the interesting information to log and how to distinguish between good and bad events taking into account that resources in medical systems are limited. How many scenarios are needed to create logs and to what extent these logs cover the integrity of the model.

Future plans include working on the analysis of real logs generated by the execution of the Fresenius infusion pump. This work aims at extracting results that can complement the analysis of the model at design level, currently under investigation [13].

Acknowledgements. The authors would like to thank prof. I. Lee, prof. O. Sokolsky, prof. K. K. Venkatasubramanian and prof. E. Vasserman for their invaluable insights.

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