

Highlights

Reliability Analysis of Multi-parameter Monitoring Systems for Intensive Care Units

Matheus Soares de Araujo¹, Leandro Dias da Silva¹, Álvaro Sobrinho², Paulo Cunha³, Leonardo Montecchi⁴

- The main power supply and the battery are the CS that present the most negative impacts on the total reliability.
- Multi-parameter monitoring systems are essential resources to support in coping pandemics such as the COVID-19.
- In emergencies (e.g., pandemics), reduced time ranges of maintenance showed to be promising.
- The model is parametric and modular, and designers can adapt it to other systems and analysis.
- This study is relevant to support the management of Intensive Care Units.

Reliability Analysis of Multi-parameter Monitoring Systems for Intensive Care Units

Matheus Soares de Araujo¹, Leandro Dias da Silva¹, Álvaro Sobrinho²,
Paulo Cunha³, Leonardo Montecchi⁴

*Computer Institute, Federal University of Alagoas, Maceió, Brazil*¹

*Federal University of the Agreste of Pernambuco, Garanhuns, Brazil*²

*Federal Institute of Alagoas, Arapiraca, Brazil*³

*Department of Computer Science, Norwegian University of Science and Technology,
Trondheim, Norway*⁴

Abstract

Multi-parameter monitoring systems in Intensive Care Units (ICUs) monitor the clinical condition of critical state patients. These Systems of Systems (SoS) comprise a set of Constituent Systems (CS) to measure parameters such as heart rate, respiratory frequency, and temperature. Due to the critical nature and relevance of ICUs, such SoS shall be as reliable as possible. That is especially true in emergencies, as the COVID-19 outbreak that resulted in the burden of health care systems. We developed a modular and parametric model to perform reliability analysis and to provide insights to assist the management of multi-parameter monitoring systems used in ICUs, also considering maintenance. First, we modeled a multi-parameter monitoring system for ICUs using the CHEMA methodology and modeling language. Afterward, we performed a reliability analysis using the CHEMA state-based analysis plugin for different scenarios. We identified that the main power supply and the battery are the CS that present the most negative impacts on reliability. In emergencies, reduced time ranges of planned maintenance, when applied during a short period, showed to be promising strategies.

Keywords: Modeling; Medical Devices; Reliability.

1. Introduction

Intensive Care Units (ICUs) are hospital environments used to improve the health care of patients that are in critical health conditions, but are still considered as recoverable, clustering medical devices and human resources [1]. Recoverable patients need constant monitoring, medical assistance, and continuous care, centralized in a single location. Multi-parameter monitoring systems are an example of typical technology used in ICUs to monitor the clinical condition of patients.

A multi-parameter monitoring system is a System of Systems (SoS) [2] used to analyze many physiological data. A monitoring system provides information to help health care professionals' in the decision-making process. An SoS coordinates autonomous Constituent Systems (CS) that provide services to achieve a specific goal that cannot be achieved by individual CSs alone [3]. Therefore, multi-parameter monitoring systems are comprised of a set of CS to measure parameters such as heart rate, respiratory frequency, and temperature. The continuous monitoring of this type of parameter is a requirement for patients in critical health conditions under treatment in ICUs. For example, the 2020 COVID-19 outbreak evidenced ICUs as essential resources to support the treatment of patients with acute lung injury. However, many countries worldwide ran out of ICUs beds and medical devices (e.g., ventilators and multi-parameter monitors) at several hospitals, due to a large number of COVID-19 severe cases [4]. Multi-parameter monitoring systems are essential resources to cope with pandemics such as the COVID-19, enabling the continuous monitoring of vital signs and providing alarms about the patient's health condition [5].

Given the critical nature and relevance of ICUs, the adopted medical devices, including multi-parameter monitors, shall be as reliable as possible. Reliability is defined as continuity of correct service [6]; from a statistical perspective, reliability can be measured as the probability of failure-free operation of a system, in a specific environment, over a given period. For example, monitoring systems shall operate using electric power grids, batteries, or generators. When the electric power grid runs out of power (a common event in low- and middle-income countries), the battery provides redundancy until the generator takes place. Lack of electricity can be frequent, depending on the region in which ICUs are located [7].

Multi-parameter monitoring systems wear out over time and may no longer function correctly. Therefore, periodic planned maintenance of this

type of system is relevant to increase the longevity and availability, especially in critical environments as ICUs, increasing the reliability, and reducing the risk of failures [8]. For example, the lack of maintenance of the medical devices of ICUs, over time, can compromise the availability of essential services, resulting in hazardous situations to patients, in addition to decreasing the number of available beds (a critical resource during pandemics). On the other hand, planned maintenance also produces a considerable impact in the costs of maintaining ICUs, especially in terms of financial planning, such that managers of ICUs should have information on the maintenance schedules, maintenance costs, and the probabilities of failure related to medical devices.

The values can differ from manufacturers' manuals under specific circumstances, such as humidity, power grid quality, maintenance, etc. The power grid's lack of quality can compromise the life cycle of electronic equipment. The lack of resources in small and medium-size hospitals avoids extended warranties contracts with the manufacturers [9]. Besides, equipment from several different manufacturers is used in the same unit. In this scenario, it is hard to establish a maintenance policy and equipment substitution decision.

In this study, we developed a modular and parametric model to perform reliability analysis of multi-parameter monitoring systems used in ICUs. The analysis results can provide insights to assist the management of those systems, considering usage and maintenance. As a walk-through analysis, we extracted information on multi-parameter monitoring systems for ICUs by interviewing a professional with more than fifteen years of experience in the maintenance of medical devices in several public and private hospitals, analyzing existing systems (e.g., [10] and [11]) and literature reviews [12, 13]. The information obtained from the expert helped us understand the problem and create the block diagram of the equipment focus of this work. Unfortunately, there is no publicly available reliability data for this domain; neither the hospitals nor the manufacturers disclose such sensitive data. We contacted a public university-maintained hospital in a large city, Hospital Universitário Professor Alberto Antunes (HUPAA/UFAL); they provided standard calibration and periodic maintenance data, but not corrective maintenance data, evidencing how difficult is to have access to such information.

We modeled a multi-parameter monitoring system for ICUs using the CHESSE Modeling Language (CHESSE-ML) and we performed the reliability analysis with the aid of the CHESSE State-Based Analysis (CHESSE-SBA)

tool, simulating different scenarios. CHESS-ML and CHESS-SBA are components of the CHESS methodology [14]. The main contribution of this paper is a modeling methodology based on the CHESS framework. We developed a parametric and modular, illustrative example model of multi-parameter monitoring systems for ICUs. Besides, we present two additional contributions: (1) discussions on reliability analysis of the system at specific intervals for different scenarios using the CHESS-SBA plugin; and (2) insights for planned maintenance strategies for multi-parameter monitoring systems from the reliability analysis.

In this work we provide a high-level reliability calculation model, organized to be modular and reusable. A modular model promotes the reuse of CSs models on other projects. A designer can develop models for other types of equipment, reusing the CSs models from our model. A parametric model is beneficial because failure probabilities are difficult to access information. Therefore, different vendors or users can use specific parameters for specific systems using the same model without any other changes. Using this model, hospitals do not need to rely on (un)available third-party data. Also, they do not need to perform complicated calculations. Finally, as the model is modular, it is easy to change it to other equipment. We used data from components such as capacitors to estimate the MTBF of the blocks. A hospital maintenance person can update the high-level SysML model with actual MTBF values.

The organization of the rest of this article is as follows. In Section 2, we discuss the related work. In Section 3, we describe the CHESS methodology, the CHESS modeling language, and the SBA analysis plugin. In Section 4, we present the model of the multi-parameter monitoring system using the CHESS-ML, while in Section 5, we show the analysis results for different scenarios. In Section 6, we discuss the analysis results. In Section 7, we conclude the paper and present future work suggestions.

2. Related work

Reliability and availability engineering [15] is a well-established field, and a wide range of analysis techniques have been developed during the last decades. Many work adopt a model-based approach [16], in which a complex system is abstracted into a mathematical model, from which reliability and availability metrics can be estimated by means of probabilistic techniques. Such approach is especially useful for critical systems, in which experimental

approaches are of limited application: access to those systems in their operational context is typically limited, and exercising the real system may be costly, dangerous or unfeasible.

Recently, Gao and Wang [17] studied a constant retrial machine system by conducting reliability and availability analysis. They calculated the reliability function and the Mean Time to Failure (MTTF) using the Laplace transforms method, discussing the optimization of the cost-effectiveness ratio to provide managerial insights. Planned maintenance guides the repair of the system. Kumar and Jain [18] presented reliability analysis of a multi-component machining system (a solar energy plant and material handling system). The authors applied the matrix method approach to analyze transient behavior, in addition to analyze the sensitivity of the system reliability and MTTF. Zhang [19] studied random weighted k-out-of-n systems by conducting reliability analysis. The author conducted reliability analysis using Bernoulli trials under different selection probabilities. Singh and Singh [20] analyzed the impact of individual component failures on the overall systems reliability using a Bayesian approach. The authors proposed a technique to determine the criticality of the components and conducted a case study on a nuclear power plant system. Closer to our work, Tsarouhas [21] conducted reliability and maintainability analysis of a hospital dialysis system. The authors presented descriptive statistics of the failures of the system's components, calculated the reliability and the maintainability using different time intervals, and discussed the results to provide insights to assist maintenance.

Manually creating reliability models is a complex task that requires specialized engineers. However, some modeling patterns are recurrent, and to a certain extent such models can be derived from the system architecture enriched with information on the failure and repair processes. Several approaches have been proposed in this direction; an extensive survey on this topic can be found in [22]. While many approaches for the automated derivation of reliability models have been defined, few of them have been implemented in a real comprehensive tool. In this paper we use the CHESSE methodology [23], implemented in an open, an open source tool developed and improved over different research projects.

Bressan et al. [14] applied the CHESSE methodology to conduct reliability analysis of a real-world hybrid automotive system. The authors modeled an hybrid automotive brake system, by specifying the system architecture, CSs, components, input and output ports, and the necessary connectors between components. Besides that, they provided an overview of how the CHESSE

methodology can be applied in the context of the ISO 26262 automotive standard. Montecchi and Gallina [24] proposed a metamodel to model safety-related properties of socio-technical systems, that is, systems whose behavior is given by the interplay of humans, organizations, and technology. The authors revised and extended the modeling concepts used in CHESSE, with the objective to support socio-technical entities, and also to provide a better integration between the CHESSE-SBA and CHESSE-FLA analysis plugins. To the best of our knowledge, there is no study applying the CHESSE methodology for the reliability analysis of medical devices.

A considerable number of studies has analyzed the safety of medical systems and the improvement of management tasks [25, 26, 27, 28]. For instance, Moura et al. [9] analyzed extended warranties for technology-intensive medical equipment using game theory to maximize the Original Equipment Manufacturer (OEM) profit and the hospital expected utility. For large hospitals the extended warranty with priority is the best choice while to medium and small hospitals the extended warranty without priority or on demand maintenance is the best choice. As an extension to their model they propose to consider the effect of subsystems and components on equipment degradation.

In Rocco et al. [29] the authors applied an approach to validate systems' reliability and illustrate how to address the limitations of previous works. As our approach, they also assess the effects of the components' reliability on the systems' reliability.

In Kim and Kim [30] the authors present stochastic models to assist the design and analysis of systems. They use the models to address the redundancy allocation problem. One of the main objectives is to maximize the reliability of systems by using different components, redundancy level, redundancy strategies. We used a similar approach, however, in our study, the stochastic models are hidden from the modeler to decrease the time-consuming and complex task required in the usage of formal languages.

Karabag et al. [31] proposed a Condition based maintenance approach to multi-component systems. They used partially observable Markov decision process formulation to optimize maintenance interventions and spare part selection. They do not take into account the uncertainty in individual components' reliability.

Hassan and Masoud [32] defined an integrated socio-technical approach to study the quantity and quality of interdependent hospitals following earthquake occurrence using a stochastic semi-Markovian process. They argue that repair resources are key to maximize the hospital's service and function-

ality.

Xia et al. [33] presented a comprehensible literature overview on prognostics and health management for advanced manufacturing paradigms. Regarding the approach related to our work, “prognostics by using mathematical models to describe the degradation mechanics or damage propagation.” they point as gap “dependence of specific domain experience and modeling techniques”, and as challenge “accuracy increase of modeling and parameter estimation, and consideration of external factors”. In our work we deal with both using the CHESSE methodology. The CHESSE modeling is based on the SysML industry standard and the stochastic Petri nets model is automatically generated from the SysML. The parameter estimation is performed by a sensibility analysis for component’s failure propagation considering specific external factors like power grid quality and availability, and humidity, that are not taken into account in the manufacturers’ manuals and maintenance plans.

Failure propagation analysis has been applied to several different domains like interdependent networks [34], mission abort policy [35], high-speed railway [36], power systems [37], cyber-physical systems [38], functional software failures [39], and Internet of Things (IoT) [40], for example.

In this paper we apply the CHESSE methodology to estimate the reliability of multi-parameter monitoring systems used in ICUs, considering usage and planned maintenance, with the objective to support the development of management strategies. We also analyzed the impact of individual component failures on the overall systems reliability. The study of the reliability of multi-parameter monitoring systems for ICUs is an application domain not yet addressed in the current state-of-the-art. This type of study is relevant to support the management of ICUs, preventing lack of resources in emergency situations such as the COVID-19 pandemic. Moreover, this analysis can be used as a warning system for planned maintenance.

3. The CHESSE Methodology and CHESSE-SBA

CHESSE [23] is methodology and toolset for the development and analysis of high-integrity systems, resulting from the effort of different research projects involving research institutions and the industry. The methodology has been implemented in an open source toolset that has been released and it is maintained as an Eclipse project under the PolarSys initiative [41].

3.1. *CHESS Modeling Language*

The CHESS methodology is centered around modeling the system architecture and its non-functional properties, and automatically applying different analysis techniques via model transformations. Modeling is done with the CHESS Modeling Language (CHESS-ML), a customized graphical language that reuses some elements from the Systems Modeling Language (SysML) [42], the Unified Modeling Language (UML) [43], and the MARTE profile [44], and also adds specific concepts to model non-functional properties. CHESS-ML supports modeling the a system at three different levels: system, software, and hardware, with each level enabling different analysis and verification plugins. In this paper we focus on the system level, which provides greater flexibility for reliability analysis.

In the system view, elements derived from SysML are mainly used, in particular Block Definition Diagrams (BDD) and Internal Block Diagrams (IBD). Following the CHESS methodology, the kinds of components that appear in the system are first specified in a BDD, and are then instantiated in one or more IBD, thus providing the possibility to reuse them.

The internal structure of the system (i.e., its architecture) is defined in an IBD where the atomic components are instantiated connected together through ports to represent their interactions.

3.2. *State-Based Analysis*

Once the system model is defined, it can be analyzed using different plugins, each applying a different analysis techniques, e.g., data flow analysis, schedulability analysis, and also dependability analysis. The CHESS State-Based Analysis plugin (CHESS-SBA) supports automated reliability analysis of a system modeled using CHESS-ML. The term “state-based” emphasize that the reliability model of the system is defined in terms of relevant states and the possible transitions between them.

In more details, CHESS SBA extracts information relevant to reliability analysis from the system model, and automatically generates a Stochastic Petri Net (SPN) [45] that represents the failure (and repair) behavior of the system. After a sequence of model transformations [46], the generated model is executed on a discrete-event simulator that calculates an estimation of the reliability metrics of interest. When analysis results are available, their are added into the original model provided as input, in a process called back-annotation.

Of course, for the analysis to be performed, reliability-related information must be added to the model of the system. To specify the failure behavior, the methodology supports probability distributions such as exponential, deterministic, uniform, normal, gamma, and Weibull. The definition of reliability information is conducted using three stereotypes that can be applied to SysML or UML elements: `SimpleStochasticBehavior`, `FLABehavior`, and `ErrorModelBehavior`. Attributes of these stereotypes, which include for example failure and repair distributions, can be specified using the MARTE Value Specification Language (VSL) syntax [44].

The `SimpleStochasticBehavior` stereotype is used to attach basic reliability information to a component. In this case, the component can only be affected by one type of internal fault, causing the component to fail immediately. In contrast, the `FLABehavior` stereotype enables the definition of a component failure behavior in terms of failure propagation logic (e.g., see [47]), that is, to specify how propagation incoming from the input ports of the component is reflected on its output ports. The `ErrorModelBehavior` stereotype enables modelers to provide more details on possible failures and errors. Details can be specified using a specific type of State Machine Diagram called `ErrorModel`, which contains information on the faults/errors/failures propagation chain within a component or block.

Finally, the CHESSE SBA plugins enables the simulation of maintenance strategies. Based on the activity concept, a maintenance strategy can define a set of activities that are executed when specific conditions are satisfied. A stereotype called `Repair` represents a maintenance activity, enabling a component instance to return to the original healthy state.

4. Multi-parameter Monitoring System Modeling

First, we conducted interviews with a professional with more than fifteen years of experience in maintenance of medical devices to elicit information on multi-parameter monitoring systems used in ICUs. The professional contributed by providing information on internal functioning, communication flows between components, and failures rates. In addition, we analyzed existing systems from available documentation (e.g., [48, 10] and [11]).

To estimate the failure rates for the blocks of the architecture, failure rates were defined for components like capacitors, based on their amount and type (tantalum or electrolytic) [13]. The specialist helped with this task. Moreover, since hospitals have no extended warranty contracts with

Healthcare Unit: HOSPITAL UNIVERSITÁRIO PROFESSOR ALBERTO ANTUNES
 Equipment Type: MONITOR

Appointment Date	Patrimony	Equipment / Brand / Model	Serial Number	Sector	Frequency (months)
Healthcare Unit: HOSPITAL UNIVERSITÁRIO PROFESSOR ALBERTO ANTUNES					
Status: Active					
Program: CALIBRATION					
01/12/2021	1588(PAT-	MONITOR MULTIPARAMETRO / DIXTAL / DX-2023	102302268	ENDO	12
01/12/2021	1182(SEM-	MONITOR MULTIPARAMETRO / DIXTAL / DX-2022 +	173303250	UTI COVID	12
01/12/2021	0399(PAT-	MONITOR MULTIPARAMETRO / DIXTAL / DX-2021	121505418	ALCON	12
01/12/2021	1515(PAT-	MONITOR MULTIPARAMETRO / DRAGER / INFINITY DELTA XL	6002302379	UTI AD	12
01/12/2021	0530(PAT-	MONITOR MULTIPARAMETRO / DIXTAL / DX-2020	161310962	CLIN MED	12
01/12/2021	1480(PAT-	MONITOR MULTIPARAMETRO / DRAGER / INFINITY DELTA XL	6002272473	UTI AD	12
01/12/2021	1502(PAT-	MONITOR MULTIPARAMETRO / PHILIPS / INTELLIVUE MX-500	DE671F5894	UTI AD	12
01/12/2021	0851(PAT-	MONITOR MULTIPARAMETRO / PHILIPS / MX-500	DE671F5903	UTI AD	12
01/12/2021	1188(PAT-	MONITOR MULTIPARAMETRO / CMOS DRAKE / MDK-2010-PLUS M	M01610201	CENTRAL EMH	12
01/12/2021	1518(PAT-HU-	MONITOR MULTIPARAMETRO / OMNIMED / OMNI-612	20001220	UTI COVID	12
01/12/2021	0681(PAT-	MONITOR MULTIPARAMETRO / DIXTAL / DX-2010	80W15136	REUMAT	12
Program: PREVENTIVE					
01/04/2022	0906(PAT-	MONITOR VIDEO / SONY / TRINITRON	6003880	GINECO	12
01/04/2022	0766(PAT-	MONITOR VIDEO / KARL STORZ / EJMILA-26-EK-1	K3ID10381	CCG	12
01/04/2022	0191(PAT-	MONITOR VIDEO / SONY / TRINITRON	6021059	PAT	12
01/06/2022	1417(PAT-	MONITOR MULTIPARAMETRO / MINDRAY / UMEC-10	KN91036570	UTI NEO	12
01/06/2022	0681(PAT-	MONITOR MULTIPARAMETRO / DIXTAL / DX-2010	80W15136	REUMAT	12
01/06/2022	1396(SEM-	MONITOR MULTIPARAMETRO / R&D MEDIUM / RD-12	20170060	UTI COVID	12
01/06/2022	1008(PAT-	MONITOR MULTIPARAMETRO / OMNIMED / OMNI-612	2079	UTI COVID	12
01/06/2022	1106(SEM-	MONITOR MULTIPARAMETRO / R&D MEDIUM / RD-12	20170058	UTI COVID	12
01/06/2022	1183(PAT-HU-	MONITOR MULTIPARAMETRO / R&D MEDIUM / RD-12	20170052	UTI COVID	12
01/06/2022	1135(SEM-	MONITOR MULTIPARAMETRO / PHILIPS / EFFICIA CM-120	CM62627582	UTI COVID	12
01/06/2022	1138(SEM-	MONITOR MULTIPARAMETRO / PHILIPS / EFFICIA CM-120	CM62627056	UTI COVID	12
01/06/2022	1137(SEM-	MONITOR MULTIPARAMETRO / PHILIPS / EFFICIA CM-120	CM62627671	UTI COVID	12
01/06/2022	1113(SEM-	MONITOR MULTIPARAMETRO / PHILIPS / SURESIGNS VM-4	US90327285	UTI COVID	12
01/06/2022	1105(SEM-	MONITOR MULTIPARAMETRO / PHILIPS / INTELLIVUE MX-500	DE671G7881	UTI COVID	12

Figure 1: Preventive maintenance and calibration log example.

the manufacturer, nor third-party maintenance contracts, they keep a detailed history of failure occurrences per equipment. Based on this list, the in-house maintenance team can estimate the failure rate to define the maintenance period for each piece of equipment. It is important to note that the humidity and the power source are not strictly controlled. In the same unit, there are different manufacturers for the same equipment. The specialist worked in the maintenance of several public and private hospitals. Based on his experience, we defined the failure rates for the blocks, as explained before, and compared them with the failure logs kept for the equipment in the hospitals. We found that the estimated values are compatible with the logs. Unfortunately, hospitals do not disclose those corrective maintenance logs. Figure 1 shows part of the preventive and calibration log as an illustrative example.

Multi-parameter monitoring systems usually consists of CSs to monitor the electrocardiogram (ECG), body temperature (thermometer), oxygen sat-

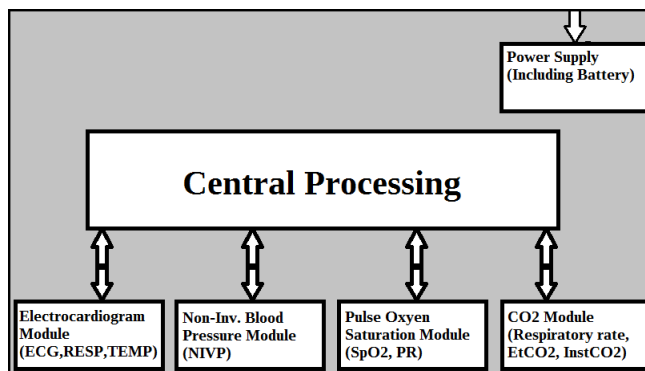


Figure 2: Block diagram of a multi-parameter monitoring system (Adapted from [48]).

uration (pulse oximeter), respiratory rate, and blood pressure. In addition, they have a main power supply (i.e., connected to the electric power grid) and battery CS. In the following sections, we present the elicited requirements along with the description of the model. It is important to note that, as the model is modular and parametric, besides the exact architecture that we model in this paper, similar system architectures can be modeled using this model as basis. The CS models can be reused and changed, and specific failure probabilities can be updated easily with little effort.

4.1. System Architecture

4.1.1. Overview

The block diagram of the multi-parameter monitoring system for ICUs is illustrated in Figure 2. We used this block diagram as a basis to model the system using the CHES-ML. The CHES-ML model contains the main block `MultiparameterMonitor`, with the CSs ECG and respiratory, thermometer, blood pressure, pulse oximeter, battery, power supply, and power supply controller. It is possible to see each CS organized with all multi-parameter monitoring system model on Figure 3. The block definition diagram for the multi-parameter monitoring system is presented on Figure 4. The `PowerSupply` block represents the power supply that connects the main system with electric power grids, while the `Battery` block represents a battery used as a redundancy for the main power supply of the monitor. Finally, the `PowerSupplyController` block represents a power controller that receives the electricity from the `PowerSupply` and `Battery` blocks, distributing it to the entire system. The multi-parameter monitoring system only be-

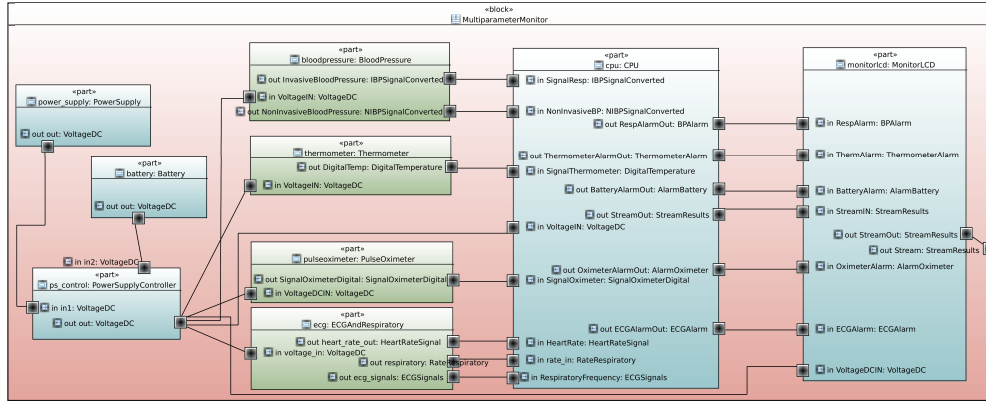


Figure 3: Highest level specification of a multi-parameter monitoring system using the internal block diagram.

comes unavailable, due to the total lack of electricity, when the main power supply and the battery are both unavailable. In ICUs, if the main power supply fails, an energy generator can be used to maintain the monitoring. The purpose of the battery is to support the transition between the main power supply and the generator, preventing the total unavailability of the system.

In addition, the main block definition diagram is composed of two more blocks: CPU and MonitorLCD. The CPU block receives and processes all data from the other CSs (e.g., power supply, heart rate, and respiratory rate). The `StreamResults` and `VoltageDC` data types support the communication flow between the existing blocks. Figure 3 presents the internal block diagram used to represent the highest level of decomposition of the multi-parameter monitoring system.

The ECG, blood pressure, thermometer, and pulse oximeter CSs require electricity, provided by the `PowerSupplyController` block. The outputs of those CSs are delivered to the CPU block for data processing. In turn, the CPU sends the processed data to the `MonitorLCD` block, using the `StreamResults` data type. The CPU also sends alarms to the `MonitorLCD`, after processing data collected from the sensors. Such alarms are generated from parameters configured by health professionals that operate the multi-parameter monitoring systems to support the treatment of specific patients (e.g., children, young person, or elderly person).

The `MonitorLCD` block represents the screen used to present real-time in-

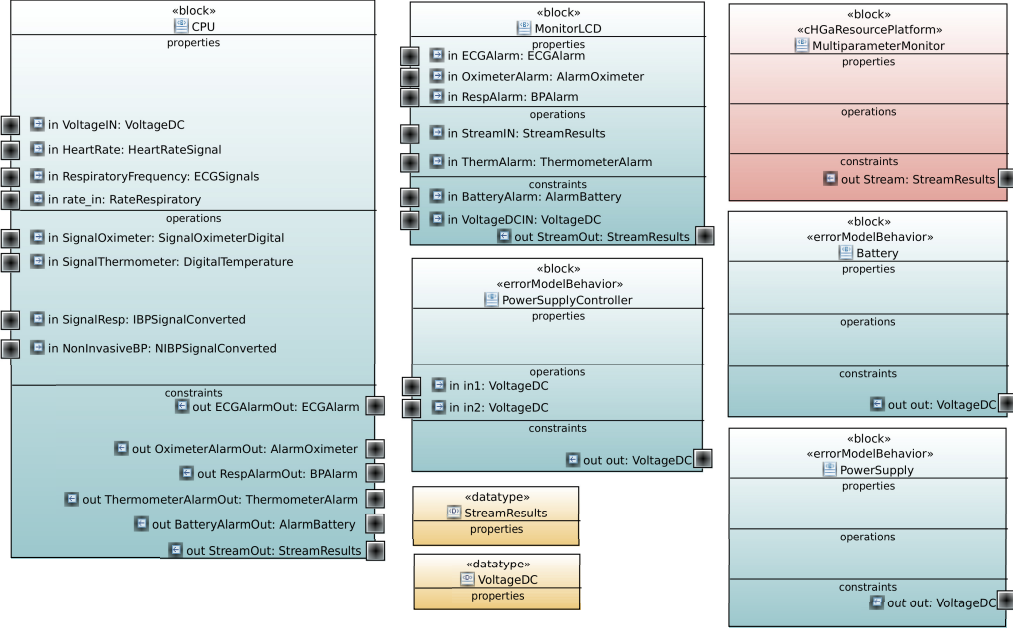


Figure 4: Block definition diagram of a multi-parameter monitoring system.

formation on the monitoring of the patient (bedside monitor). The `MonitorLCD` component, powered by the `PowerSupplyController` block, displays all the information provided by the CPU. The `MonitorLCD` is composed of an output port (`StreamOut`) that transmits information and alarms. In the remaining of this section, we detail some of the models of the internal components of the system. The complete version of the CHES-ML model of multi-parameter monitoring systems is available in an online repository [49].

4.1.2. ECG and respiratory constituent system

The ECG and respiratory constituent system consists of electrodes, respiratory rate monitor, instrumentation amplifier, filters, and analog-to-digital converters. The model is composed of blocks that represents `Electrodes`, `Amplifiers`, `Filters`, and `Converters`. We also defined the data types called `VoltageDC`, `HeartRateSignal`, `RespFSignal`, `SignalBioElectric`, and `ECGAlarm`, which are the types used in the communication ports of the corresponding blocks.

The `RespiratoryRate` block represents the computation of respiratory rate based on the impedance of electrodes [50]. This modeling decision relied

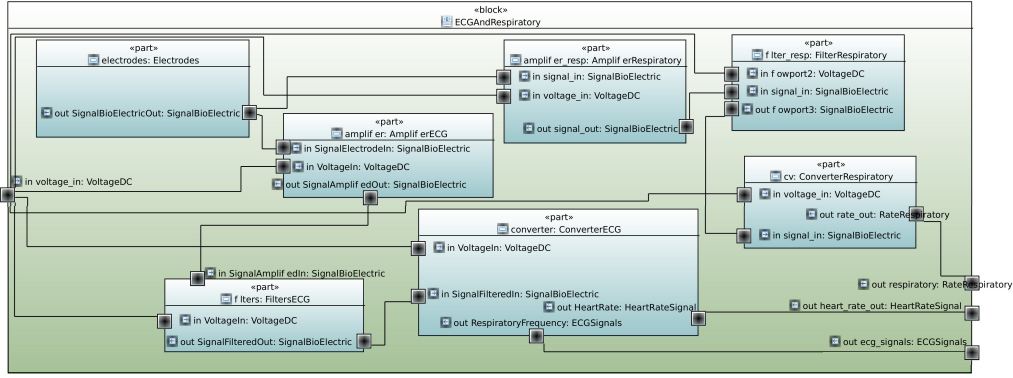


Figure 5: Internal block definition diagram for the ECG and respiratory constituent system.

on specifications of similar systems and literature reviews that consider the thoracic impedance method [51]. Thus, the `RespiratoryRate` block receives the impedance of electrodes from the `Electrodes` block, computes the respiratory rate, and sends the results through the `respiratory` output port of the system. In addition, the `Amplifier`, `Filters`, and `Converter` blocks require the main power supply and battery, using the communication ports defined by the `VoltageDC` data type, representing a continuous power supply.

Therefore, the `Amplifier` block receives an analog signal collected from the `Electrodes` block, using the `SignalBioElectric` data type. The amplified signals are used as inputs to low-pass, high-pass, and notch filters (`Filters` block). Afterward, the filtered signals are the inputs for `Converter` block, enabling the conversion of the analog signals to the digital domain. Therefore, two more outputs of this constituent system are produced, using the `HeartRateSignal` and `ECGSignal` data types. Figure 5 presents the internal block diagram where the communication between blocks is defined, using the previously specified ports.

4.1.3. Thermometer constituent system

The organization of components (i.e., parts) is similar to that presented for the ECG and respiratory. The block definition diagram is composed of the `Filter`, `Converter`, `Amplifier`, and `SensorPTC` blocks, in addition to the data types `DigitalTemperature`, `ThermometerSignalCaptured`, and `ThermometerAlarm`. This constituent system depends on the power supply to start working, that is, capturing signals from the patients to measure temper-

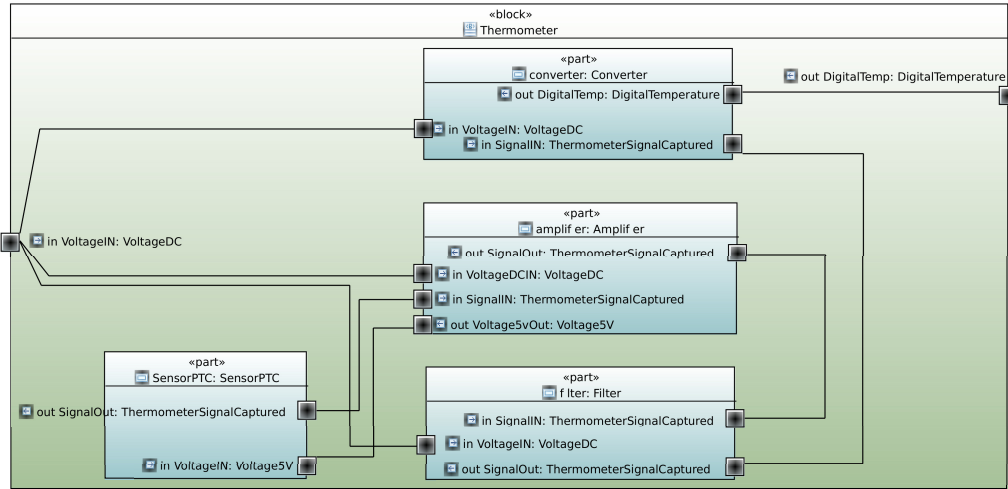


Figure 6: Internal block diagram for the `Thermometer` constituent system.

ature. Electricity is provided for the `Converter`, `Amplifier`, and `Filter`. Afterward, the `Amplifier` block sends an energy signal to the `SensorPTC` block to start collecting analog signals.

The `SensorPTC` block captures the signals related to the temperature and sends them to the `Amplifier` block, which amplifies the signal. The amplified signal is sent to the `Filter` block to remove existing noises. The `Filter` block sends the amplified signals to the `Converter` block to represent the analog signals in the digital domain (the output of the constituent system). Figure 6 presents an internal block diagram, containing the communication flow between the blocks of the `Thermometer` constituent system.

4.1.4. *Pulse oximeter constituent system*

The `pulse oximeter` constituent system measures the oxygen saturation of patients under monitoring in ICUs. We defined the `Leds`, `PhotoReceptor`, `Amplifier`, `Filters`, and `Converter` blocks to represent the internal parts of the constituent system. A block called `PulseOximeter` represents the highest hierarchical level, containing the communication flow between internal parts. The blocks `Leds` and `PhotoReceptor` represent the sensors for collecting analog signals from patients. We also defined the data types `Voltage5V`, `LigthCaptured`, `SignalOximeterDigital`, and `AlarmOximeter` to enable the communication flow between internal parts.

Figure 7 presents the internal block diagram, containing the communica-

tion flow and organization of the blocks of the `pulse oximeter` constituent system. The correct functioning of this constituent system depends on electricity from the main power supply and battery. The `Amplifier` block sends an energy signal to the `Leds` and `PhotoReceptor` blocks, with a voltage less than 5V, using the `Voltage5V` data type. The `Leds` block generates a light on the patient's skin to enable the `PhotoReceptor` block to capture the patient's analog signal related to the oxygen saturation. The `PhotoReceptor` block sends the signals to the `Amplifier` block for amplification. Then, the amplified signals are processed by the `Filters` block to remove noises. Finally, the signals are converted from the analog domain to the digital domain using the `Converter` block (the output of the constituent system).

4.1.5. Blood pressure constituent system

The `blood pressure` constituent system is composed of the `Sensor`, `Amplifier`, `Filter`, and `Converter` internal blocks. The `BloodPressure` is the block with the highest hierarchical level of this constituent system, which represents all the communication flows of the internal blocks to measure the blood pressure of patients. We also defined the data types `SignalCaptured`, `BloodPressureSignal` and `BPAAlarm`. For example, the `BloodPressureSignal` data type represents the signals converted to blood pressure information for the patient.

Figure 8 presents the internal block diagram of the `blood pressure` constituent system, which contains the communication flows between the internal blocks. This constituent system requires electricity, for the `Converter`,

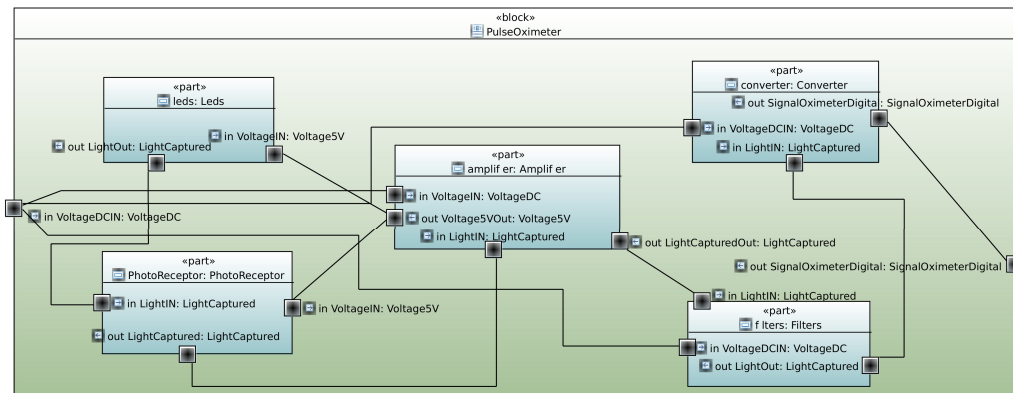


Figure 7: Internal block diagram for the `pulse oximeter` constituent system.

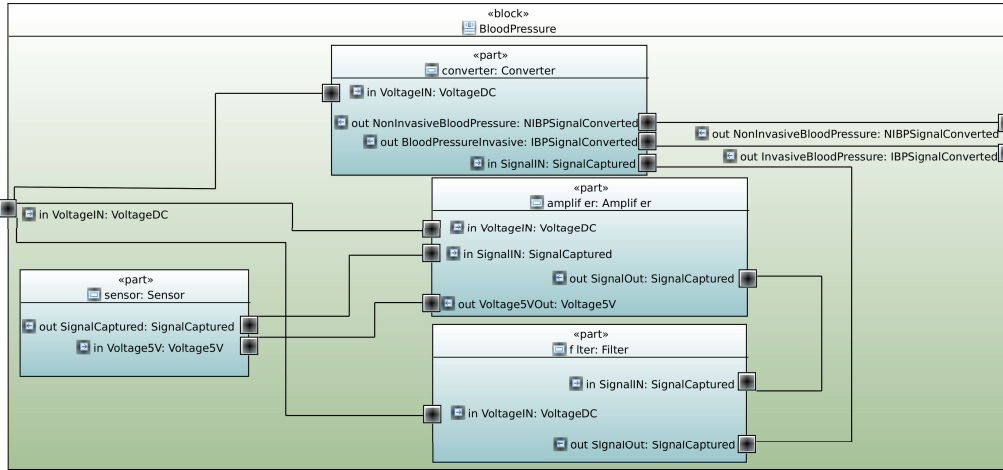


Figure 8: Internal block diagram of the `blood pressure` constituent system.

`Amplifier`, and `Filter` blocks to start operating. The `Amplifier` block receives the electricity provided by the power supply, and converts it to a voltage less than 5V, sending the voltage to the `Sensor` block (to start capturing the patient’s signals). When the patient’s analog signals are captured, the `Sensor` block sends them to the `Amplifier` block, which sends the amplified signal for the `Filter` block. Similarly to the others CS, filters are applied to remove noises from the captured signals. The signals are then provided, as outputs, to the analog-to-digital `Converter` block. As highlighted, after conversion, the constituent system returns the blood pressure information in a converted signal to digital.

4.2. Error Models

4.2.1. Battery error model

Figure 9 presents the state-based error model that represents the behaviors of the `battery` constituent system. The model contains two error states: `BatteryFault`, representing a defect in the battery; and `LackofCharge`, representing the discharge of the battery. The initial state is the `healthy` state, indicating that the system is in a desired condition.

The transition to an error state is triggered by an internal fault that occurs after a certain amount of time; in this model we assume it is distributed according to the exponential distribution. The occurrence of the fault results in a probabilistic choice between `BatteryFault` and `LackofCharge`. Transitions

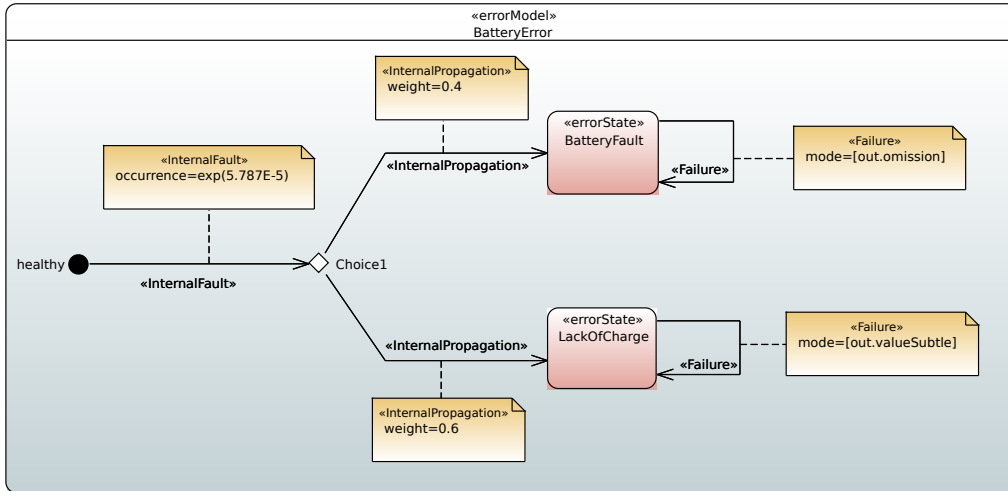


Figure 9: State-based error model of the battery constituent system.

to these error states have different weights, that represent a higher probability of occurrence for LackofCharge (60%) than for BatteryFault (40%). In this model, the two failure modes are represented by the omission failure mode (BatteryFault) and by the valueSubtle failure mode (LackofCharge).

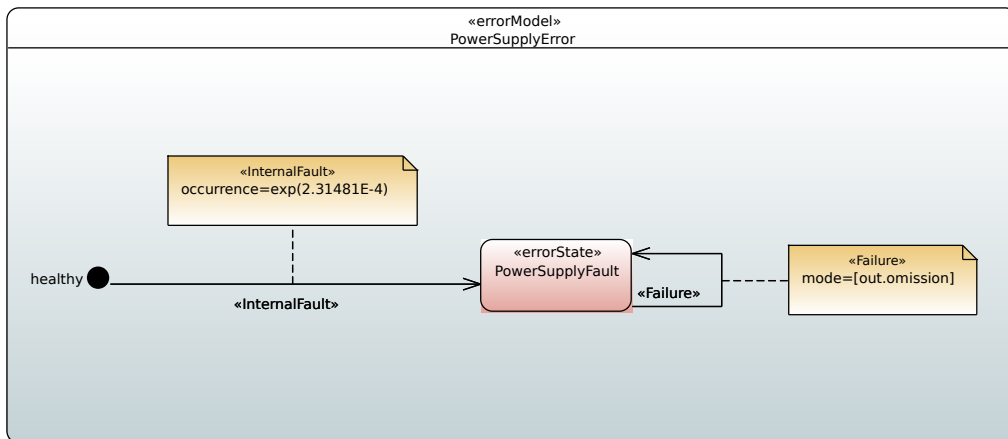


Figure 10: State-based error model of the main power supply constituent system.

4.2.2. Main power supply error model

Figure 10 presents the state-based error model that represents the behaviors of the main `power supply` constituent system. Similar to the model presented in Figure 9, we defined a desired state (`healthy`) and an error state (`PowerSupplyFault`). The `PowerSupplyFault` state represents a defect or lack of electricity in the electric power grid. In this case, we only used the `omission` failure mode to represent the failure. The exponential probability distribution illustrated in this model is also used during the reliability analysis.

4.2.3. Power supply controller error model

The `power supply controller` constituent system manages the switch between the main `power supply` and the `battery`; as such, it is impacted by their failures. Figure 11 presents the state-based error model that represents the behavior of the `power supply controller` constituent system.

The initial state of this model is a `healthy` state, representing a generic desired condition of the system. This error model also contains two error states (i.e., deviations from nominal state): `BatteryFault`, representing a defect or lack of charge in the battery (i.e., `omission` or `valueSubtle` failure modes); and `NoEnergyAvailable`, representing the lack of electricity in the electric power grid. However, only the second state produces a failure on the output port `out`, meaning that the multi-parameter monitoring system is left without power (i.e., it becomes unavailable) only if both the main power supply and the redundant power supply (battery) become unavailable.

5. Reliability Analysis and Results

In this study, we assumed that all the components fail according to an exponential distribution, which is a common assumptions for electronic components in reliability analysis. In CHESS, this is modeled by adding the `SimpleStochasticBehavior` stereotype with the proper parameter to the model components presented in Section 4. The parameter (i.e., rate) of the exponential distributions has been set based on the known values of Mean Time Between Failure (MTBF) for the different components. These values have been obtained by interviewing an experienced professional in maintenance of medical devices in addition to the literature review [13].

The failure rate for each kind of components of CSs the multi-monitor system is shown in Table 1. We assume that different instances of the same

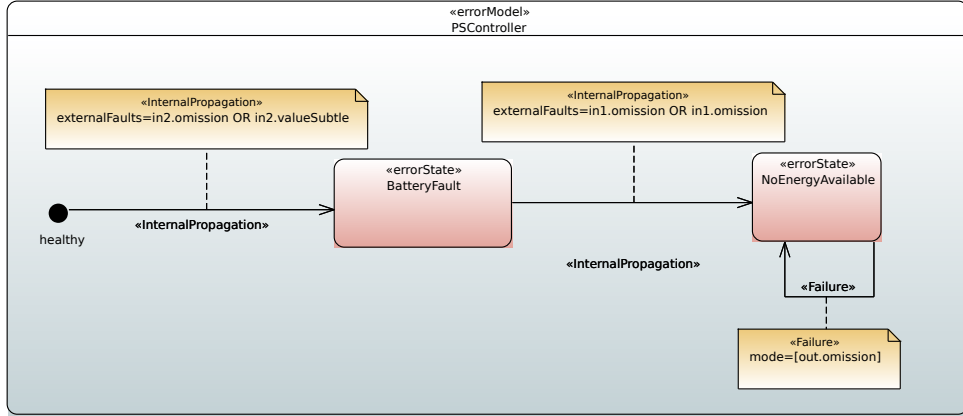


Figure 11: State-based error model of the power supply controller constituent system.

Table 1: Constituent Systems and their exponential probability distributions.

Component	MTBF	Failure Rate (λ)
Electrodes	4,320 hours (6 months)	$\exp(2.31481e-4)$
Led's	4,320 hours (6 months)	$\exp(2.31481e-4)$
Sensors	4,320 hours (6 months)	$\exp(2.31481e-4)$
Photoreceptor	4,320 horas (6 months)	$\exp(2.31481E-4)$
Main power supply	4,320 hours (6 months)	$\exp(2.31481e-4)$
Power supply controller	4,320 hours (6 months)	$\exp(2.31481e-4)$
Filters	1,7280 hours (2 years)	$\exp(5.787e-5)$
Battery	17,280 hours (2 years)	$\exp(5.787e-5)$
Amplifier	0,1% in 5 years	$\exp(2.3E-8)$
Converter	0,1% in 5 years	$\exp(2.3E-8)$

component, used in different constituent systems, have the same failure distribution. For example, different instances of amplifiers, filters, and converters can be found as parts of the CSs ECG And respiratory, thermometer, pulse oximeter, and blood pressure.

The model is evaluated by discrete-event simulation, using the automated evaluation facility of the CHES-SBA plugin. For all experiments, we defined a confidence interval of 10% and a confidence level of 99%. We conducted the reliability analysis comparing no maintenance and corrective maintenance.

The first analysis considers seven evaluation scenarios, and no maintenance activities performed (Table 2). Furthermore, we compare the reliability of the system when considering power redundancy (i.e., grid and battery),

Table 2: Reliability analysis results, without maintenance, with and without redundancy of power supply (i.e., main power and battery).

Usage Time	No Redundancy	Power Redundancy
12 days	8.583000e-01	9.988000e-01
3 months	3.274000e-01	9.505000e-01
6 months	1.070000e-01	8.560000e-01
9 months	3.395440e-02	7.585000e-01
12 months	1.149509e-02	6.508000e-01
18 months	1.180366e-03	5.017000e-01
24 months	1.146667e-04 (*)	3.814000e-01

with a normal system without redundancy (i.e., no battery or depleted battery). More specifically, we applied both CHESS-SBA analysis approaches for 12 days (i.e., mean duration of ICUs hospitalization of COVID-19 patients), 3 months, 6 months, 9 months, 12 months, 18 months, and 24 months. Only the 24 months scenario did not achieve the specified confidence level of 99%, represented in the table by (*). Figure 12 illustrates the reliability variation over time based on the results presented in Table 2. Note that time here is operation time, e.g., “6 months” mean 6 months of *continuous uninterrupted operation* of the equipment, which therefore produces a conservative estimate.

In the second analysis we consider the same seven usage scenarios, however, this time considering planned maintenance of the **main power supply**, **battery**, and **power supply controller CSs**. We consider two maintenance scenarios: every 6 months and every 12 months. We defined these maintenance period based on the interviews with the expert. In this analysis we considered redundancy between the battery and the main power supply. As in the previous experiment, we ran the analysis for 12 days, 3 months, 6 months, 9 months, 12 months, 18 months, and 24 months. In addition, to improve the discussion presented in the next section, Table 4 describes the same seven scenarios, however, considering reduced time ranges for planned maintenance of 1 month and 3 months.

This type of analysis is relevant in the context of emergency situations such as COVID-19 outbreaks, considering that viruses are usually seasonal. For example, in the case of the COVID-19 pandemic, planning maintenance of medical devices used in ICUs beforehand may assist hospitals in reducing the negative impact of medical device shortages during a new wave of the disease. This type of scenario is also relevant for other seasonal viruses, mainly in

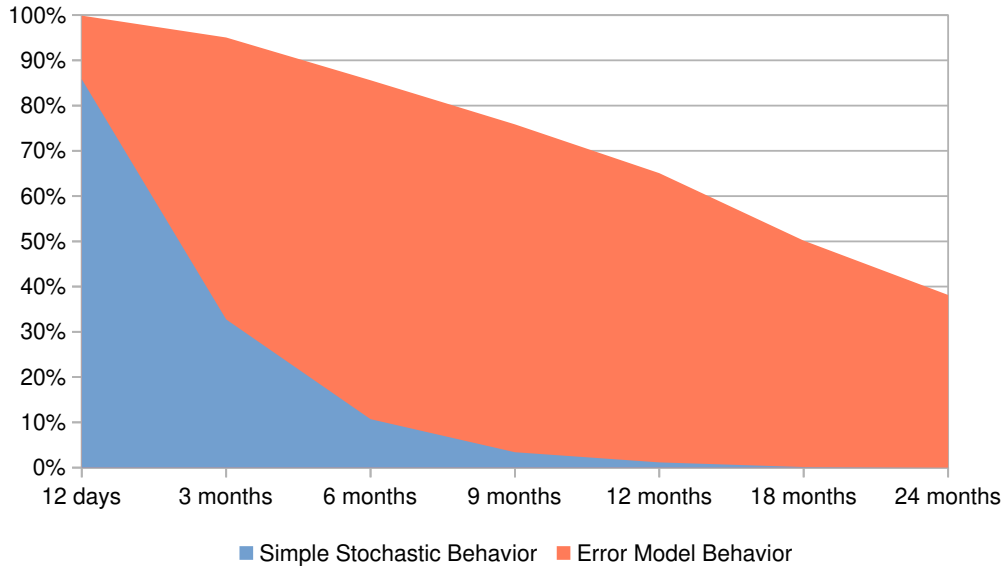


Figure 12: Reliability variation over time, without maintenance, for simple stochastic behavior and error model behavior.

low- and middle-income countries, which suffer from critical shortages of medical devices. To summarize the planned maintenance impacts, Figure 13 illustrates the reliability variation over time, with maintenance (i.e., every 1 month, every 3 months, every 6 months, and every 12 months) and with no maintenance, based on the results presented in Table 3 and Table 4.

6. Discussion

Some characteristics related to the environment and operators may negatively impact the reliability of multi-parameter monitoring systems, such as low quality of electric power grid and incorrect inputs of parameter values. However, such external actors are out of the scope of this study. Therefore, we focused on the internal components of the systems. As defined in the CHESS methodology, we have some assumptions when building and analyzing the model. The faults in the CS are independent of each other. The fault activation delay is zero. The propagation path follows the flow ports with zero delays.

We analyzed the impacts of CS failures on the reliability of a multi-parameter monitoring system. The main power supply has the highest impact

Table 3: Reliability analysis results with redundancy of power supply, with planned periodic maintenance for different scenarios and periods.

Usage Time	6 months	12 months
12 days	9.988000e-01	9.988000e-01
3 months	9.505000e-01	9.505000e-01
6 months	8.560000e-01	8.560000e-01
9 months	8.163000e-01	7.585000e-01
12 months	7.512000e-01	6.508000e-01
18 months	6.605000e-01	5.792000e-01
24 months	5.888000e-01	4.434000e-01

Table 4: Reliability analysis results with redundancy of power supply, with reduced time ranges for planned maintenance.

Usage Time	1 month	3 months
12 days	9.988000e-01	9.988000e-01
3 months	9.803000e-01	9.505000e-01
6 months	9.646000e-01	9.093000e-01
9 months	9.420000e-01	8.701000e-01
12 months	9.372000e-01	8.381000e-01
18 months	9.104000e-01	7.759000e-01
24 months	8.919000e-01	7.374000e-01

on the probability of failure, followed by the power supply controller and battery. When the power supply controller fails, the entire system is affected. The impact of the remaining CS in the entire system is almost the same because they are composed of similar components (i.e., amplifiers, filters, and converters). The main difference between the CS (`ECGAndRespiratory`, `Thermometer`, `Blood pressure`, and `PulseOximeter`) is the number of sensors used in the specification.

In the basic model, not considering redundancy of power supply (Table 2, column 2), the probability that after 288 hours (12 days) the system has not failed is still relatively high (85.83%). That is the meantime of ICUs hospitalization of COVID-19 patients [52]. As usage time increases, the probability of failure increases considerably. For example, after 18 months, reliability reduces to 0.11%. Note that in this model there is no redundancy, and the failure of any components propagates instantly, causing a failure of the entire system.

The inclusion of power supplies redundancy, using the error model be-

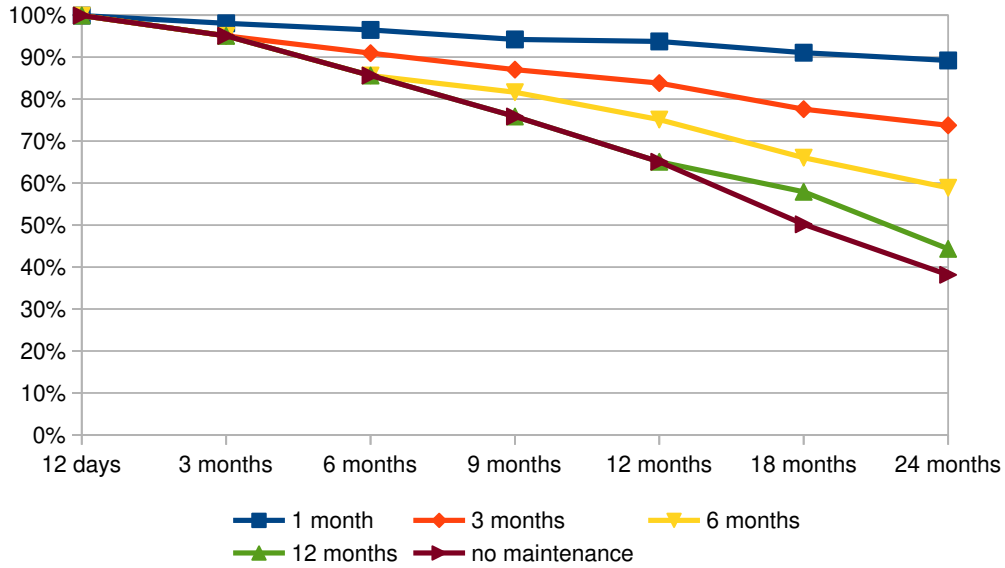


Figure 13: Reliability variation over time, without maintenance and with maintenance (i.e., every 1 month, 3 months, 6 months, and 12 months).

havior approach, with no maintenance, increased the system reliability for all usage time scenarios (Table 2, column 3). This happened because of the failure behavior modeled in Figure 9, Figure 10, and Figure 11. When the battery (Figure 9) or main power supply (Figure 10) fail, a failure mode is emitted in the output port of these CSs, requiring the power supply controller (Figure 11) to verify the availability of electricity from the other source. If both CSs fail, the multi-parameter monitoring system becomes unavailable. For example, this redundancy for the three-months scenario increased the reliability from 32.74% (no redundancy) to 95.05%. For the 24-months scenario, reliability increased from 0.011% to 38.14%. For emergency scenarios, the reliability increase is relevant for managing the impacts on the shortages of medical devices in ICUs. Note also that considering power redundancy the reliability for the 12-days scenarios (COVID-19 scenario) increases to 99.88%, which is greatly improved over the value of 85.83% without redundancy.

If planned maintenance of the **main power supply**, **battery**, and **power supply controller** CSs is considered, for a standard period of time (6 or 12 months) the reliability increases considerably (Table 3). For example, in the 9-months scenario, when applying a periodic maintenance activity every

6 months the reliability increased from 75.85% to 81.63%. In a real-world scenario (e.g., the COVID-19 pandemic), periodic maintenance can decrease even more the shortages of medical devices in ICUs when compared to the results with no planned maintenance (Table 2, column 3). Therefore, the benefits of planned maintenance of only three CS of the system are high, showing the importance of the analysis to assist managers in planning maintenance strategies. The planned maintenance cost is low (e.g., cleaning and replacing capacitors) and decreases if concentrated on the highest failure probability CS.

The choice between 6 or 12 months depends on the financial or human resources of a specific hospital. For example, in low- and middle-income countries, there are many public hospitals in precarious conditions. In non-pandemic scenarios, 12 months may be enough to provide acceptable reliability (i.e., considering non-continuous operation of the equipment). In fact, for the 24-months scenario, there is a relatively low reduction in reliability (-14.54%) if applying maintenance every 12 months instead of every 6 months. Otherwise, periodic maintenance of 12 months is the best scenario. It is important to note that we assume that, after a maintenance activity, the system comes back to the *as new* state. That means that, for this model version, we do not take into account the accumulated degradation of the equipment. Moreover, we assume that maintenance success probability is 95% and the activity has a 5 minutes duration.

We also analyzed two more planned maintenance schedules (Table 2) to improve the discussion and provide insights to guide the definition of maintenance strategies considering pandemic ICUs scenarios. First, we use three months for the 24-months scenario; the reliability increased from 38.14% (no maintenance) to 73.74% (maintenance). When we use one month, the reliability increased from 38.14% (no maintenance) to 89.19% (maintenance). Therefore, there is a 15.45% increase in the reliability from one to three months of periodic maintenance. For a pandemic ICUs scenario, this is important due to the seasonality of viruses known as waves. For example, in March 2020, the world health organization declared a pandemic due to COVID-19 outbreaks, the first wave. At the end of October 2020, some European countries announced lockdown measures due to the new reported COVID-19 outbreak, the second wave, a difference of only eight months between the first and second waves. Besides, up to October 2020, Brazil and the USA were still facing the first wave.

Reduced time intervals for periodic maintenance can help avoid the short-

ages of medical devices in ICUs, considering the short periods between waves (i.e., eight months) or the unclear finishing point of the first one. For example, if the equipment is purchased by a hospital at the beginning of the pandemic, with periodic maintenance of six months, the reliability for nine months is 81.63%. For three months, the reliability increases to 87.01%, while for one month, the reliability increases to 94.20%. The reliability increases 12.57%, from one to six months, for the nine-month scenario (i.e., within the time window of the second wave in Europe). That indicates possible benefits in defining emergency maintenance plans for pandemic/epidemics situations, even for low- and middle- income countries.

7. Conclusions

In this study, we developed a modular and parametric model to analyze the reliability of a multi-parameter monitoring system for Intensive Care Units (ICUs). We calculated the reliability using different modeling approaches and scenarios using the CHEMA methodology. The inclusion of a power supply redundancy positively impacted the reliability of systems for all analyzed scenarios. Using the reliability analysis, we identified that the main power supply and the battery are the CSs that present the most negative impacts on the total reliability of the entire system in failure situations. In non-pandemic (or epidemic) situations, the planned maintenance with a periodicity of 6 months and 12 months present a relevant impact in increasing the reliability of such systems. In pandemics situations, reduced time ranges of planned maintenance, when applied during a short period, showed to be a promising strategy to increase the reliability of the multi-parameter monitoring system for ICUs. Therefore, the analysis presented in this study is relevant for managers of ICUs for planning maintenance strategies to address emergencies such as the COVID-19 pandemic.

Despite the use of the CHEMA methodology to analyze the reliability, the results, and discussions that we presented can be helpful to other medical devices, such as respirators. We interviewed a maintenance professional with more than fifteen years of experience to define the failure probabilities of the CS but, as the model is parametric, it is possible to easily configure the model based on a specific system parameter, enabling new reliability calculations. Moreover, as the model is modular, the CS (sub)models presented in this work can be reused or adapted to analyze other kinds of medical devices.

The main difficulty in developing this kind of study is to access real failure probabilities of market devices. Either they are specific to certain technology (e.g., electrolytic and tantalum capacitors) or high-level business-related metrics (e.g., equipment recall rate). As future work, we plan to investigate failure probabilities of real market devices for the CSs, and to compare the results with the one obtained in this work. Our intuition is that even for approximated values, the results are still helpful, and it is not necessary to have vendor-specific probabilities. Another future work is to analyze other kinds of medical systems reusing some of the CS used in this work. Finally, we will perform a qualitative evaluation of our approach with real maintenance strategies used in a local hospital.

Acknowledgements

This study was financed in part by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - Brasil (CAPES) - Finance Code 001. The authors would like to thank the Hospital Universitário Professor Alberto Antunes (HUPAA-Ufal) for their contribution to this research.

References

- [1] X. Liao, B. Wang, Y. Kang, Novel coronavirus infection during the 2019–2020 epidemic: preparing intensive care units—the experience in sichuan province, china, *Intensive Care Medicine* 46 (2020) 357–360.
- [2] M. Jamshidi (Ed.), *System of Systems Engineering*, John Wiley & Sons, 2008.
- [3] D. el Diehn I. Abou-Tair, A. Khalifeh, S. Alouneh, R. Obermaisser, Incremental, distributed, and concurrent service coordination for reliable and deterministic systems-of-systems, *IEEE Systems Journal* (2020) 1–12.
- [4] G. Grasselli, M. Greco, A. Zanella, G. Albano, M. Antonelli, G. Bellani, E. Bonanomi, L. Cabrini, E. Carlesso, G. Castelli, S. Cattaneo, D. Cereda, S. Colombo, A. Coluccello, G. Crescini, A. F. Molinari, G. Foti, R. Fumagalli, G. A. Iotti, T. Langer, N. Latronico, F. L. Lorini, F. Mojoli, G. Natalini, C. M. Pessina, V. M. Ranieri, R. Rech, L. Scudeller, A. Rosano, E. Storti, B. T. Thompson, M. Tirani, P. G. Villani,

- A. Pesenti, M. Cecconi, Risk factors associated with mortality among patients with covid-19 in intensive care units in lombardy, italy, *JAMA internal medicine* (2020).
- [5] D. K. Tempe, G. C. Khilnani, J. C. Passey, B. L. Sherwal, Challenges in preparing and managing the critical care services for a large urban area during covid-19 outbreak: Perspective from delhi, *Journal of Cardiothoracic and Vascular Anesthesia* (2020).
- [6] A. Avižienis, J.-C. Laprie, B. Randel, C. Landwehr, Basic concepts and taxonomy of dependable and secure computing, *IEEE Transactions on Dependable and Secure Computing* 1 (2004) 11–33.
- [7] I. L. Millar, Hyperbaric intensive care technology and equipment, *Diving Hyperb Med* 45 (1) (2015) 50–6.
- [8] A. Subhan, Equipment Maintenance, Biomedical, American Cancer Society, 2006. doi:<https://doi.org/10.1002/0471732877.emd108>.
- [9] M. das Chagas Moura, J. M. Santana, E. L. Droguett, I. D. Lins, B. N. Guedes, Analysis of extended warranties for medical equipment: A stackelberg game model using priority queues, *Reliability Engineering & System Safety* 168 (2017) 338–354. doi:<https://doi.org/10.1016/j.res.2017.05.040>.
- [10] Gima vital signs monitors, [Online; accessed 16 December 2020] (2020). URL <https://bit.ly/34BQbkq>
- [11] Intellivue mx600 and mx700 patient monitor, [Online; accessed 16 December 2020] (2020). URL <https://bit.ly/350pyrF>
- [12] S. R. Division, Rome Laboratory Reliability Engineer’s Toolkit: An Application Oriented Guide for the Practicing Reliability Engineer, Vol. 1, The Rome Laboratory, 1993.
- [13] D. of Defense, MIL-HDBK-217F, Military Handbook: Reliability Prediction of Electronic Equipment, Department of Defense, Washington, DC, 1991.

- [14] L. P. Bressan, A. L. de Oliveira, L. Montecchi, B. Gallina, A systematic process for applying the chess methodology in the creation of certifiable evidence, in: IEEE European Dependable Computing Conference, 2018, pp. 49–56.
- [15] A. B. Kishor S. Trivedi, Reliability and Availability Engineering, Cambridge University Press, 2017.
- [16] D. M. Nicol, W. H. Sanders, K. S. Trivedi, Model-based evaluation: from dependability to security, IEEE Transactions on Dependable and Secure Computing 1 (1) (2004) 48–65. doi:10.1109/TDSC.2004.11.
- [17] S. Gao, J. Wang, Reliability and availability analysis of a retrial system with mixed standbys and an unreliable repair facility, Reliability Engineering & System Safety 205 (2021) 107240.
- [18] P. Kumar, M. Jain, Reliability analysis of a multi-component machining system with service interruption, imperfect coverage, and reboot, Reliability Engineering & System Safety 202 (2020) 106991.
- [19] Y. Zhang, Reliability analysis of randomly weighted k-out-of-n systems with heterogeneous components, Reliability Engineering & System Safety 205 (2021) 107184.
- [20] P. Singh, L. Singh, Impact analysis of change in component reliabilities in safety-critical systems, Quality and Reliability Engineering International 35 (6) (2019) 2051–2065.
- [21] P. H. Tsarouhas, Reliability analysis into hospital dialysis system: A case study, Quality and Reliability Engineering International 29 (8) (2013) 1235–1243.
- [22] S. Bernardi, J. Merseguer, D. C. Petriu, Dependability modeling and analysis of software systems specified with uml, ACM Comput. Surv. 45 (1) (2012) 2:1–2:48. doi:10.1145/2379776.2379778.
URL <http://doi.acm.org/10.1145/2379776.2379778>
- [23] S. Mazzini, J. M. Favaro, S. Puri, L. Baracchi, Chess: an open source methodology and toolset for the development of critical systems., in: EduSymp/OSS4MDE@ MoDELS, 2016, pp. 59–66.

- [24] L. Montecchi, B. Gallina, Safeconcert: A metamodel for a concerted safety modeling of socio-technical systems, in: M. Bozzano, Y. Papadopoulos (Eds.), *Lecture Notes in Computer Science*, Vol. 10437, Springer, 2017, pp. 129–144.
- [25] G. K. Kaya, M. F. Hocaoglu, Semi-quantitative application to the functional resonance analysis method for supporting safety management in a complex health-care process, *Reliability Engineering & System Safety* 202 (2020) 106970. doi:<https://doi.org/10.1016/j.ress.2020.106970>.
- [26] K. Reddy, D. Byrne, D. Breen, S. Lydon, P. O’Connor, The application of human reliability analysis to three critical care procedures, *Reliability Engineering & System Safety* 203 (2020) 107116. doi:<https://doi.org/10.1016/j.ress.2020.107116>.
- [27] M. C. E. Simsekler, A. Qazi, M. A. Alalami, S. Ellahham, A. Ozonoff, Evaluation of patient safety culture using a random forest algorithm, *Reliability Engineering & System Safety* 204 (2020) 107186. doi:<https://doi.org/10.1016/j.ress.2020.107186>.
- [28] M. C. E. Simsekler, C. Rodrigues, A. Qazi, S. Ellahham, A. Ozonoff, A comparative study of patient and staff safety evaluation using tree-based machine learning algorithms, *Reliability Engineering & System Safety* 208 (2021) 107416. doi:<https://doi.org/10.1016/j.ress.2020.107416>.
- [29] C. M. Rocco Sanseverino, J. E. Ramirez-Marquez, Uncertainty propagation and sensitivity analysis in system reliability assessment via unscented transformation, *Reliability Engineering & System Safety* 132 (2014) 176–185. doi:<https://doi.org/10.1016/j.ress.2014.07.024>.
- [30] H. Kim, P. Kim, Reliability models for a nonrepairable system with heterogeneous components having a phase-type time-to-failure distribution, *Reliability Engineering & System Safety* 159 (2017) 37–46. doi:<https://doi.org/10.1016/j.ress.2016.10.019>.
- [31] O. Karabağ, A. S. Eruguz, R. Basten, Integrated optimization of maintenance interventions and spare part selection for a partially observable multi-component system, *Reliability Engineering & System Safety* 200 (2020) 106955. doi:<https://doi.org/10.1016/j.ress.2020.106955>.

- [32] E. M. Hassan, H. Mahmoud, An integrated socio-technical approach for post-earthquake recovery of interdependent healthcare system, *Reliability Engineering & System Safety* 201 (2020) 106953. doi:<https://doi.org/10.1016/j.ress.2020.106953>.
- [33] T. Xia, Y. Dong, L. Xiao, S. Du, E. Pan, L. Xi, Recent advances in prognostics and health management for advanced manufacturing paradigms, *Reliability Engineering & System Safety* 178 (2018) 255–268. doi:<https://doi.org/10.1016/j.ress.2018.06.021>.
- [34] Y. Wu, Z. Chen, X. Zhao, H. Gong, X. Su, Y. Chen, Propagation model of cascading failure based on discrete dynamical system, *Reliability Engineering & System Safety* 209 (2021) 107424. doi:<https://doi.org/10.1016/j.ress.2020.107424>.
- [35] G. Levitin, L. Xing, L. Luo, Influence of failure propagation on mission abort policy in heterogeneous warm standby systems, *Reliability Engineering & System Safety* 183 (2019) 29–38. doi:<https://doi.org/10.1016/j.ress.2018.11.006>.
- [36] W. Huang, X. Kou, Y. Zhang, R. Mi, D. Yin, W. Xiao, Z. Liu, Operational failure analysis of high-speed electric multiple units: A bayesian network-k2 algorithm-expectation maximization approach, *Reliability Engineering & System Safety* 205 (2021) 107250. doi:<https://doi.org/10.1016/j.ress.2020.107250>.
- [37] S. Yang, W. Chen, X. Zhang, W. Yang, A graph-based method for vulnerability analysis of renewable energy integrated power systems to cascading failures, *Reliability Engineering & System Safety* 207 (2021) 107354. doi:<https://doi.org/10.1016/j.ress.2020.107354>.
- [38] C. Zhang, X. Xu, H. Dui, Analysis of network cascading failure based on the cluster aggregation in cyber-physical systems, *Reliability Engineering & System Safety* 202 (2020) 106963. doi:<https://doi.org/10.1016/j.ress.2020.106963>.
- [39] C. A. Thieme, A. Mosleh, I. B. Utne, J. Hegde, Incorporating software failure in risk analysis part 2: Risk modeling process and case study, *Reliability Engineering & System Safety* 198 (2020) 106804. doi:<https://doi.org/10.1016/j.ress.2020.106804>.

- [40] G. Zhao, L. Xing, Reliability analysis of iot systems with competitions from cascading probabilistic function dependence, *Reliability Engineering & System Safety* 198 (2020) 106812. doi:<https://doi.org/10.1016/j.ress.2020.106812>.
- [41] Eclipse CHES, Part of the Eclipse PolarSys project, <https://projects.eclipse.org/projects/polarsys.chess>.
- [42] Object Management Group, OMG Systems Modeling Language, formal/19-11-01, version 1.6 (December 2019).
- [43] Object Management Group, OMG Unified Modeling Language (OMG UML), formal/17-12-05, version 2.5.1 (December 2017).
- [44] Object Management Group, UML Profile for MARTE: Modeling and Analysis of Real-time and Embedded Systems, formal/19-04-01 (April 2019).
- [45] G. Ciardo, R. German, C. Lindemann, A characterization of the stochastic process underlying a stochastic Petri net, *IEEE Transactions on Software Engineering* 20 (7) (1994) 506–515. doi:10.1109/32.297939.
- [46] L. Montecchi, P. Lollini, A. Bondavalli, A Reusable Modular Toolchain for Automated Dependability Evaluation, in: *7th International Conference on Performance Evaluation Methodologies and Tools (VALUE-TOOLS 2013)*, Torino, Italy, 2013, pp. 298–303.
- [47] M. Wallace, Modular architectural representation and analysis of fault propagation and transformation, *Electron. Notes Theor. Comput. Sci.* 141 (2005) 53–71. doi:<http://dx.doi.org/10.1016/j.entcs.2005.02.051>.
- [48] Gima multi-parameter patient monitor user manual, [Online; accessed 03 June 2021] (2018). URL gimaitaly.com/DocumentiGIMA/Manuali/EN/M35134EN.pdf
- [49] Multi-parameter monitoring system model with the chess methodology, Available online on <https://bit.ly/3mAQi5O> (2020).
- [50] C. Redmond, Transthoracic impedance measurements in patient monitoring, Tech. Rep. MS-2458, Analog Devices (2013).

- [51] J. N. Wilkinson, V. U. Thanawala, Thoracic impedance monitoring of respiratory rate during sedation – is it safe?, *Anaesthesia* 64 (4) (2009) 455–456.
- [52] G. Grasselli, A. Zangrillo, A. Zanella, M. Antonelli, L. Cabrini, A. Castelli, D. Cereda, A. Coluccello, G. Foti, R. Fumagalli, G. Iotti, N. Latronico, L. Lorini, S. Merler, G. Natalini, A. Piatti, M. V. Ranieri, A. M. Scandroglio, E. Storti, M. Cecconi, A. Pesenti, Baseline Characteristics and Outcomes of 1591 Patients Infected With SARS-CoV-2 Admitted to ICUs of the Lombardy Region, Italy, *JAMA* 323 (16) (2020) 1574–1581.