A Model for Architecture Centric Development of Automated External Defibrillators

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***Abstract*— Due to complex safety requirements, medical devices must obey rigorous standards. In the development of these devices, modeling techniques must be used to analyze the design decisions in agreement with such standards. In this paper, we present a Matlab/Simulink specification as an analytical model for Automated External Defibrillators (AEDs) and its integration with a Model Based Systems Engineering (MBSE) approach through descriptive models. The proposed model allows us to analyze algorithms for decision of shock application, performance of circuits when obtaining the required voltage, safety of the produced energy for shock delivery and characteristics of signals produced at the output of the AED. The model is composed of modules with interfaces specification, allowing safe module replacement and the assessment of the module influence over the system at a technical level.**

***Keywords*— Model Based Systems Engineering, Automated External Defibrillator, Assessment, Performance, Safety.**

I. Introduction

Technological advances and cost decrease of medical devices are turning these products essential to increase life expectance and quality. Automated External Defibrillator (AED) is a consolidated therapy for ventricular fibrillation/tachycardia treatment, which are the cardiac arrhythmias with highest incidences of fatal cases [1]. In the treatment of such conditions, any delay in the application of the defibrillation shock may be fatal, since each delay of one minute to apply the shock implies in a loss of 7% to 10% in the surviving chances [2].

People are more confident in using AEDs, and non-specialized rescuers can use them. However, this implies in more sophisticated design decisions. In addition, development and validation of technologies embedded into these devices must follow rigorous standards and meet safety requirements.

For promoting the quality of AED systems, it is suggested the use of model-based tools, allowing the assessment of functional and safety requirements. This paper describes an open model for AED, developed using Matlab/Simulink tools that can assess safety features ranging from ECG signal processing to the current values and energy levels released to the patient. Beyond safety features, the proposed model allows assessing the decision process for the application of the defibrillation pulse, internal values of the involved voltage/current to obtain the necessary energy for the pulse application and the waveform to be released to the patient chest. Furthermore we show the connections of these artifacts to software architecture and failure propagation models.

This paper is divided as follows. In Section VI we present the related works. In Section III we present the proposed model. In Section IV we present the obtained results when performing simulation using the proposed model. In Section V we discuss the main perspectives for engineering processes when using the model. In Section VI we give details the integration with Model Based Systems Engineering (MBSE) approach towards traceability and safety assurance. Finally, in Section VII we present the conclusions and future developments.

II. Related Work

On the subject of reference open models for medical devices, the most notorious initiative is the Generic Infusion Pump project [3], which is supported by FDA, UPenn and Fraunhofer CESE, to promote safety models in different classes of infusion pumps. This work provides several types of system and safety engineering artifacts, such as Simulink models, widely employed in many types of research in the medical device domain. Although we recognize the valuable contributions of this initiative, we suffered when trying to make use of it because of the lack of traceability between its artifacts, turning it difficult to synchronize different types of research in the system and safety engineering fields. There is no similar AED initiative and we are trying to fill this gap by providing models following an architecture-centric approach through the mentioned MBSE project. Such model can be evolved to deal with fault injection approaches. Soon all these presented models will be delivered at the NUTES website[1] and

[1] nutes.uepb.edu.br

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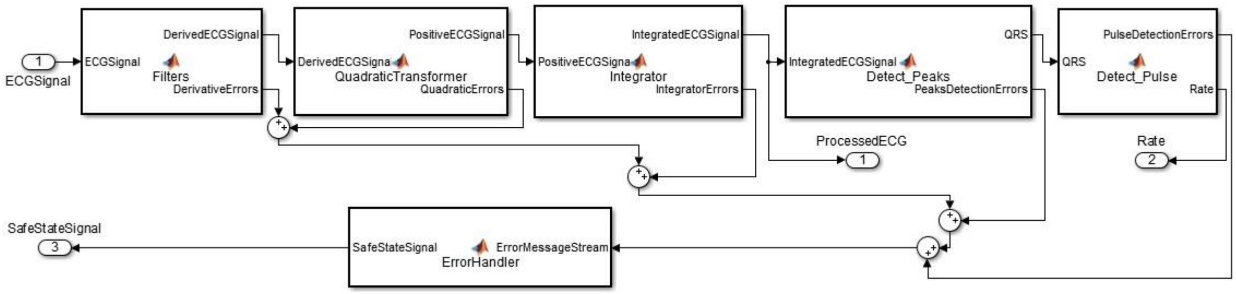

Fig. 1 - Signal Analyzer module decomposition

a team of engineers will be available for providing support to evolve it, in a partnership with the Brazilian Health Ministry.

Other works model specific features of defibrillators, however we were not able to find a complete model or specification that allowed us to analyze system properties and module interaction. This is the main claim of this work. Most works are related to the decision making procedure for shock application. In [4], we have an algorithm based on time delay, processing the ECG signal by using time windows of 8 seconds, tested using traditional ECG databases. In [5] we have concerns with performance and consumption, in order to have implementation in common microcontrollers. [6] uses complexity signal measurements, as employed in this work, for decision of shock application with a time window of 7 seconds and analyzed over 200 ECG signals. In all these cases, we need to have a patient under rest conditions and no CPR (cardiopulmonary resuscitation) is applied, with less success of the therapy. Only in [7] we have the actuation of rescuers for applying CPR.

Some hardware modules are also modeled, as in [8]. The authors present the simulation and analysis of a DC-DC flyback, by increasing voltage from 12 V to 2.1 kV. In [9] we have evidences that the biphasic waveform is more efficient than monophasic waveform. In this case, the authors employed computational models for myocardium, submitting to monophasic and biphasic stimulations.

In this sense, it makes clear that this work reuses pieces of information of several recent developments on defibrillators research and delivers to the scientific community model-based artifacts able to satisfy many scientific and industrial purposes.

III. THE PROPOSED MODEL

The proposed model is composed of three functional modules: Signal Analyzer, Charge and Discharge. The user interface in the Matlab work window requires the file name or an input stream with the ECG data. After receiving the ECG data, the Signal Analyzer module applies the Pan-Tompkins [10] algorithm to extract patient's cardiac frequency.

The frequency value will be used in the CPLX detection of ventricular fibrillation/tachycardia algorithm [11] to extract the signal complexity. In case of the measured complexity to be higher than the normal range, as proposed in [12], the Signal Analyzer module sends a signal for the Charge module to start the process of obtaining the necessary energy. Otherwise, it sends a message to the user interface informing that the defibrillator pulse is not necessary, avoiding the charge of the capacitor through a signal sent to the Charge module.

The Signal Analyzer module is implemented as Matlab scripts structured following the *Pipes and Filters* design pattern as shown in Fig. 1. We divided each phase of the processing as a filter and there is one *ErrorHandler* module, catching, reporting and processing each existing error during the signal analysis process. Each phase of the signal processing, from the signal normalization until the detection of RR intervals, can be visualized through automatic generated graphics. Such processing finishes with the complexity signal calculation through the Lempel-Ziv algorithm. As higher the complexity signal is, the more we assume it has a more chaotic behavior, becoming similar to an ECG signal with arrhythmias characteristics of interest for treatment.

The switching control at the primary side is performed by a quadratic waveform source. If the signal sent by the Signal Analyzer module indicates the necessity of charging, this source connects to the gate of the switch. Otherwise, we turn on a switch to a signal level that keeps it open, avoiding the current flow in the primary of the transformer.

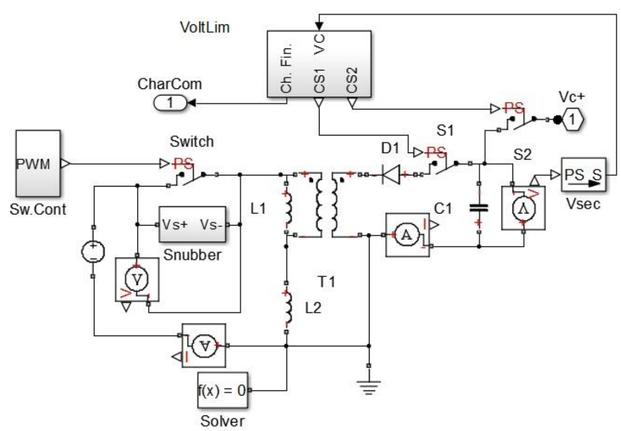

Fig. 2 - Charge Module

We also designed a dissipative Snubber in order to absorb the voltage peaks generated by the switching of inductors in DC-DC converters. The capacitor to be charged by this converter is connected to the secondary of the transformer via a switch, and for the output, we repeat this technique, having two complementary switches.

Control over the secondary switch is performed by a comparison between the voltage of the charge capacitor and its designated voltage. In this sense, while the required voltage is not obtained, the charge capacitor remains connected to the secondary of the transformer. When the required voltage is reached, the charge capacitor is disconnected and connected to the next stage, guaranteeing the required voltage and the release of the energy only when the correct value is reached, as shown in Fig. 3.

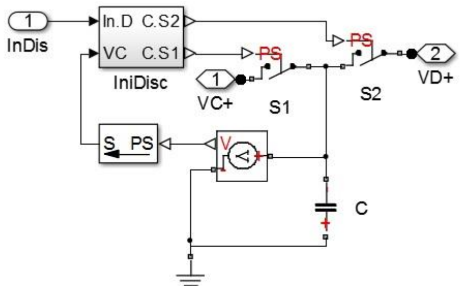

Fig. 3 - Control keys of the charge capacitor

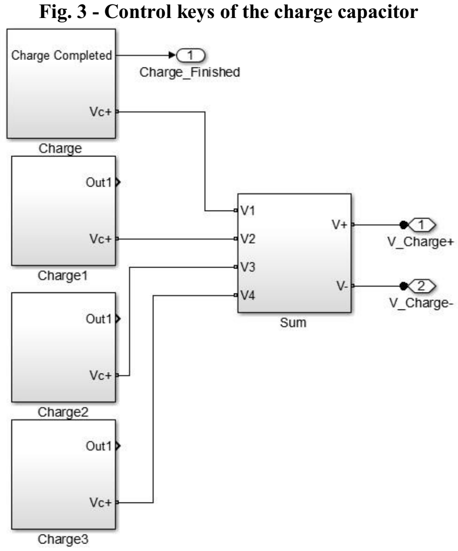

Fig. 4 – Integration between Charge Modules

To decrease circulating currents in the circuit, and the consequent losses and component wear by Joule effects, this elevation of voltage is obtained by the sum of four modules such as the previous one. We have an equal division of efforts necessary for obtaining the required voltage. The output of these modules is delivered to an adder using the classical configuration with operational amplifiers and resistors. Such configuration has as advantage the possibility of adjusting the charges in case of any module failure, having as disadvantage the additional costs originated by these redundancies, as shown in Fig. 4.

The obtained voltage charges the discharge capacitor in the Discharge module. Similar to the Charge module, after this capacitor becomes charged, it is disconnected from the charging circuit and connected to the circuit that will deliver energy to the patient, offering a safer process as a whole.

Biphasic waveform has superior efficacy verified by physiologists [13], therefore it was employed to deliver the energy to the patient, represented by her thoracic impedance. We employed an H bridge, as shown in Fig. 5, that is kept conducting in the positive direction until we reach the delivery of the half of the energy and then the direction is inverted. This control uses a border detector and a latch in order to maintain the switches activated by an exact period, as shown in Fig. 6.

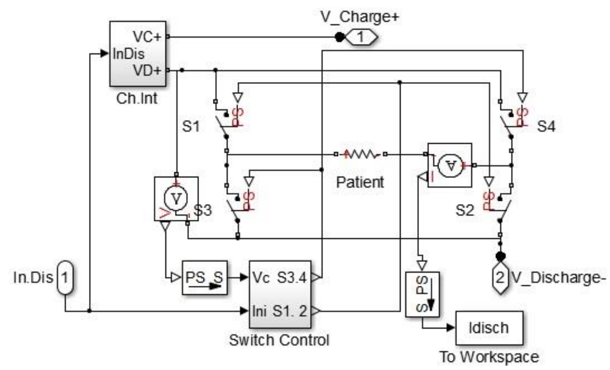

Fig. 5 - Discharge module

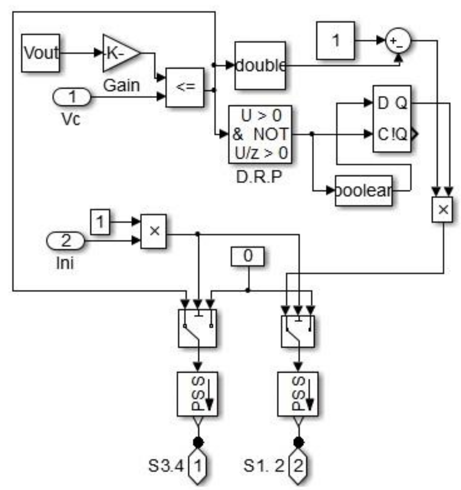

Fig. 6 - Control keys of the discharge current

Energy, delivered in both positive and negative semi cycles, is calculated based on the current to be applied to the patient and her transthoracic impedance. This is performed in order to test the quality of the charging/discharging processes in a functional point of view, when comparing the energy that was delivered to the patient and the one specified by the user, as well as the fragments delivered in positive and negative semi cycles.

IV. RESULTS

The analyzed ECG signals were obtained from the Beth Israel Hospital (MIT-BIH) and Creighton University

Ventricular Tachyarrhythmia Database (CUDB), available at the Physionet website [14]. Two signals were processed to evaluate Pan-Tompkins and CPLX algorithms, and we obtain a cardiac frequency of 114 bpm for the first one and 75 bpm for the last one, as well as the higher measure of Lempel-Ziv complexity of 0.1694 and 0.0656 respectively. Therefore, the first one was characterized as ventricular tachycardia and the second as normal.

Concerning the charging circuit behavior, we obtained graphics shown in Fig. 7, with time axis limited to the period required to finish the capacitors charging, approximately 25 milliseconds. The magnitudes relative to the secondary have inverted polarities due to the change in the direction of the diode in the secondary.

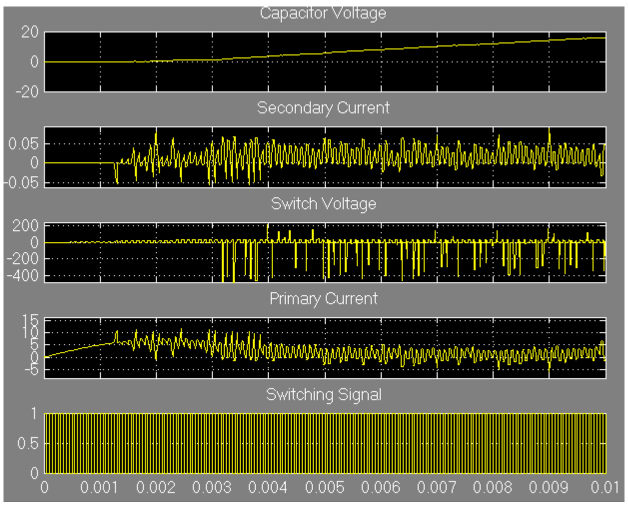

Fig. 7 - Measuring the Charge module

The behavior of the Discharge module can be analyzed observing Fig. 8. In the upper graph, we have the Biphasic Truncated Exponential waveform current delivered to the patient. In the lower graphic we have the charge and discharge of the charge capacitor, where we can verify that the process takes 2 seconds as a whole, from the reading of the signal to the discharging of the necessary energy for the defibrillator pulse. The total discharging of the capacitor ensures this.

V. PERSPECTIVES

Due to the modularity and organization of the proposed model, we are able to both assess parameters of the involved components in the circuits and to measure the electrical magnitudes in each point of the circuits, allowing the usage of the model as a black box.

We can also replace some modules or existing components in the model for obtaining more impressive experimental results. For example, we can assess the lifetime of some critical components according to their workload. In this sense, we could evaluate the lifetime of a battery, replacing the current DC source for a time evolutionary model, and to verify how many discharges are possible in a plenty full situation, and also assess what is the variation of this charge with heavy usage.

Another contribution is to allow the analysis of semiconductors usage in the switching process. We can obtain improvements with an analysis based on the switching frequency as well as the saturation of specific transformers for defibrillators.

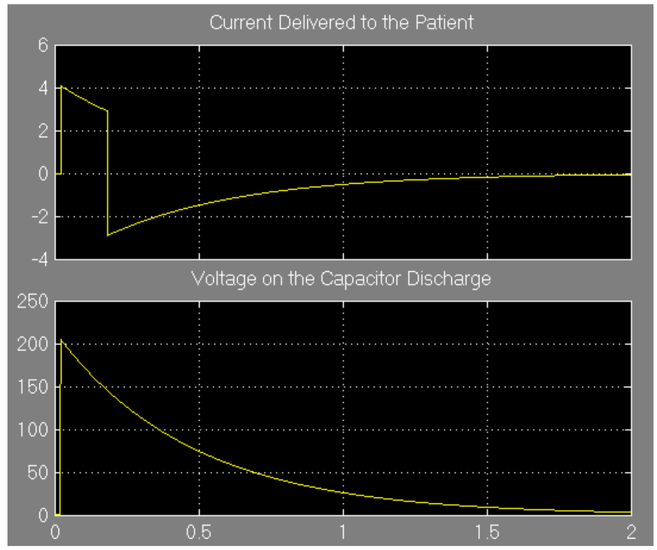

Fig. 8 - Output waveforms

Finally, the last contribution is the analysis of the error between the required energy and the delivered energy. According to standards such as ANSI/AAMI DF80 from 2003 and IEC 60601-2-4 from 2005, this error could not be more than 15% or 3 Joules, depending on the case. According to our analysis, this implies in an error range between the required energy and the delivered energy is between 100 to 300 Joules, as shown in Fig. 9 and Fig. 10. We can observe in Fig. 9 that the maximum error in the current model occurs when the required energy is 103 Joules and 0.3% and the maximum error in energy is 0.56 Joules that occurs when the required energy is 216 Joules.

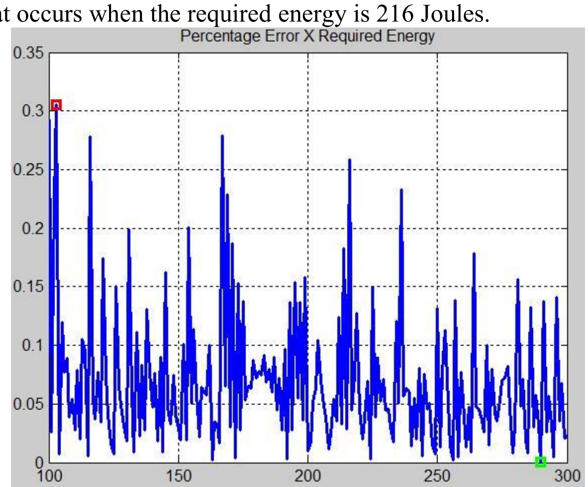

Fig. 9 - Percentage error between requested and delivered energy

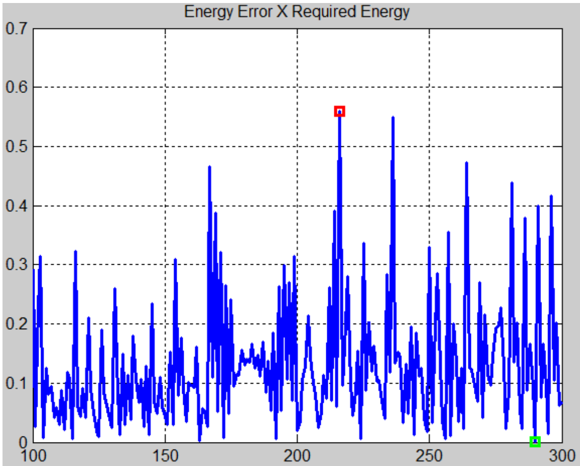

Fig. 10 - Absolute error between requested and delivered energy

VI. INTEGRATION WITH MODEL BASED SYSTEMS ENGINEERING

This section intends to give contextual information on the role of the Matlab/Simulink specification over the MBSE process for medical devices that is being defined at NUTES. The development flow follows the IEC 62304 [15] for the systems engineering process and ISO 14971 [16] for the safety engineering process. One interesting result obtaining when employed such model can be found in [17].

The AED system is structured into views. Firstly, we have requirements analysis, definition of use cases and exception cases, and the early system analysis. Therefore, we expanded the items involved in the System Design Model in order to show the Components Interface Design, that defines the communication between modules presented previously in the Matlab/Simulink model of the AED.

Fig. 11 presents the main specification of components interfaces at system level using SysML notation, at the system design level. For each specific system and subsystem we have a controller interface (AED Control) that manages the state machines of all the involved components providing a scheduling policy. An operating system is the main entity inside this controller. At the left of the AED Control we have the Shock Generator subsystem that contains the Charge and Discharge modules realized in Simulink. At the right side of the AED Control we have the Signal Analyzer module and the Matlab specifications are analytic models for this descriptive specification. Moreover, we have interfaces with other architectural items, such as User Interface, Sensors, Pads, Display, etc. The software layer contains generated code by Enterprise Architect and Matlab tools for embedded microcontrollers such as ADSP Blackfin from *Analog Devices*, and the hardware layer contains specifications for the instrumentation of power electronics circuits.

Fig. 12 shows an excerpt of risk analysis according to ISO 14971. For the hazard *Overshocking*, as described in Table 1, we have the association of this danger to the use case *Normal operation of the AED*, the main parameter to be controlled is *Energy*, the *Hazardous Situation* occurs when we associate the *Pads* to the *Patient* and the harm is suffered by the *Patient*.

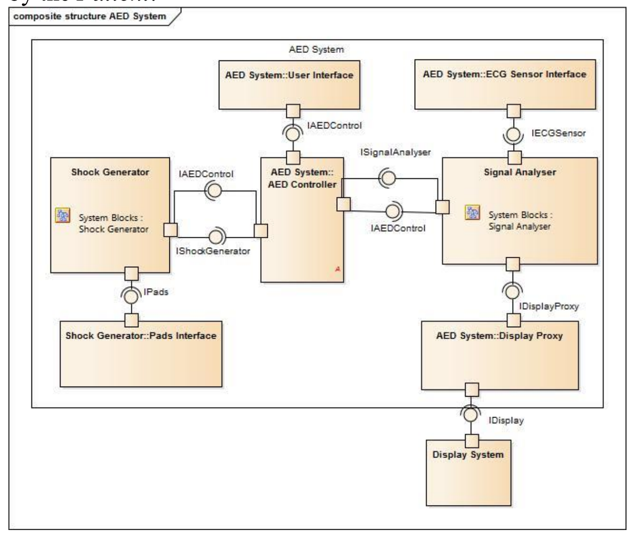

Fig. 11 - Specification of interfaces between components in the AED

Table 1. Hazard description

Hazard	Overshocking
Cause	The energy delivered is over 15% or 3 Joules the estimated one.
Safety requirements	The delivered energy cannot vary more than 15% or 3 Joules.
Fault categories	Class C: Death or SERIOUS INJURY is possible.
Alarm	Deviation is over or equal 14%.
Warning	Deviation is over or equal 10%.
Information	Deviation is over or equal 7%.
Failure mode	When alarmed, go to the safe state to not deliver any energy at all and reset variables and parameters to default.
Failure distribution	If we capture energy with a deviation, send the deviation as entrance for the algorithm to process the energy to be delivered; we send a command to deliver the energy with a deviation; we will also send the deviation as an entrance to the monitoring function and we deviation might not be detected. (fail in all those software units).

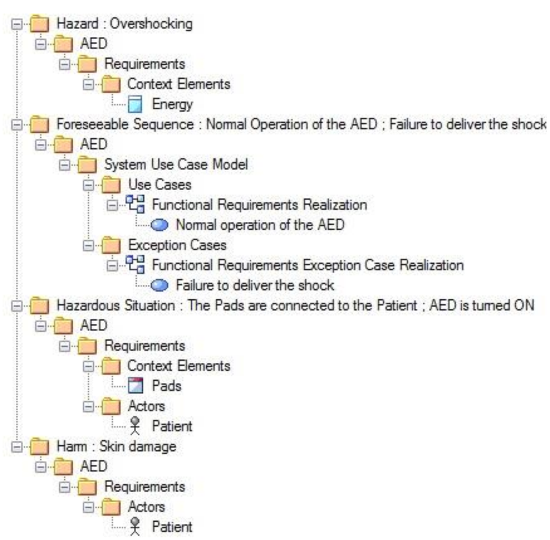

Fig. 12 - Identification of Overshocking hazard according to ISO 14971

The *Overshocking* hazard occurs as a result of the combination of intermediate and basic events inside the Shock Generator, which is also composed of software entities inside their controllers. In the Charge module, the main causes stem from the loss of ability of the Charge Controller to maintain the stability of the energy transfer process. In the Discharge module, the main causes stem from the wear of hardware components and the failure in detecting and mitigating problems due to the high level of energy to be delivered originated in the Charge module. Finally, all these controllers have embedded software, where logical problems such as data error or wrong control flow might generate events that could somehow contribute somehow to raising the undesirable top event. The Fault Tree in Fig. 13 summarizes these analysis.

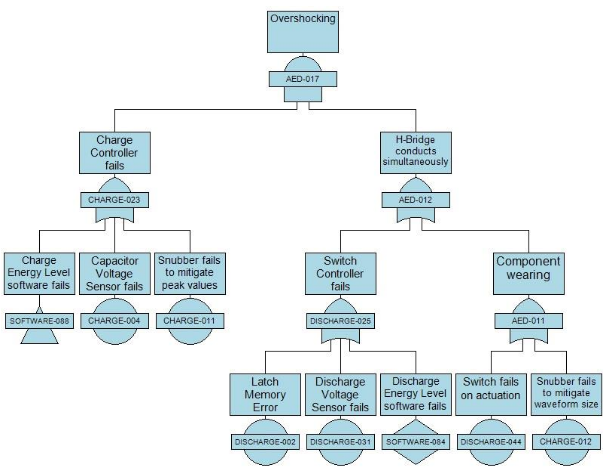

Fig. 13- Fault Tree Analysis for the Overshocking hazard

VII. Final Remarks

In this paper, we presented a modular model for an AED that allows us to assess performance, safety and reliability of these devices. In each module, we focus on the circuits and in systems and safety engineering artifacts to implement its functionality. Curves produced at the output of the AED were presented and information about the overall MBSE process gave to the reader the importance of this artifact in a safety-critical systems engineering context.

The modularization of the presented model enables various types of analysis, especially the influence of changing a specific module in the performance of the whole AED system through an exhaustive interface specification of components.

Results of this research are part of an initiative from Brazilian Health Ministry for technological transfer projects from well-consolidated manufacturers to research institutes, in order to retain the expertise of manufacturing medical devices. In this context, we are receiving and improving methodologies for manufacturing AEDs from the LIFEMED[2] company and providing new improvements.

References

[1] Newman, Mary. “Sudden Cardiac Arrest: A Healthcare Crisis”. http://www.sca-aware.org/about-sca.

[2] American Heart Association. “ECC Guidelines – Part 4: The Automated External Defibrillator”. American Heart Association Journals. ISSN: 1524-4539. http://circ.ahajournals.org/content/102/suppl_1/I-60.full

[3] David Arney, Raoul Jetley, Paul Jones, Insup Lee, and Oleg Sokolsky. 2007. Formal Methods Based Development of a PCA Infusion Pump Reference Model: Generic Infusion Pump (GIP) Project. In *Proceedings of the 2007 Joint Workshop on High Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability* (HCMDSS-MDPNP '07). IEEE Computer Society, Washington, DC, USA, 23-33.

[4] Amann, A., Tratnig, R., & Unterkofler, K. (2007). Detecting ventricular fibrillation by time-delay methods. Biomedical Engineering, IEEE Transactions on, 54(1), 174-177.

[5] Dell’aquila, C. R., Cañadas, G. E., Sistena, C., & Laciar, E. (2015). Implementation of a Simple Real-Time Algorithm for Ventricular Fibrillation Detection in a Microcontroller. In *VI Latin American Congress on Biomedical Engineering CLAIB 2014, Paraná, Argentina 29, 30 & 31 October 2014* (pp. 655-658). Springer International Publishing.

[6] Zhang, X. S., Zhu, Y. S., Thakor, N. V., & Wang, Z. Z. (1999). Detecting ventricular tachycardia and fibrillation by complexity measure. *Biomedical Engineering, IEEE Transactions on*, *46*(5), 548-555.

[7] Li, Y., Bisera, J., Weil, M. H., & Tang, W. (2012). An algorithm used for ventricular fibrillation detection without interrupting chest compression. Biomedical Engineering, IEEE Transactions on, 59(1), 78-86.

[8] Kewei, H., Jie, L., Ningjun, F., Yuebin, L., Xiaolin, H., & Luo, W. (2009, July). Modeling analysis and simulation of high-voltage flyback DC-DC converter. In*Industrial Electronics, 2009. ISIE 2009. IEEE International Symposium on*(pp. 813-818). IEEE.

[9] Fishler, M. G., Sobie, E. A., Tung, L., & Thakor, N. V. (1995). Cardiac responses to premature monophasic and biphasic field stimuli: results from cell and tissue modeling studies. *Journal of electrocardiology*, *28*, 174-179.

[10] Pan, Jiapu, and Willis J. Tompkins. "A real-time QRS detection algorithm." Biomedical Engineering, IEEE Transactions on 3 (1985): 230-236.

[11] Lempel, Abraham, and Jacob Ziv. "On the complexity of finite sequences." Information Theory, IEEE Transactions on 22.1 (1976): 75-81.

[12] Amann, Anton, Robert Tratnig, and Karl Unterkofler. "Reliability of old and New Ventricular Fibrillation Detection Algorithms for Automated External Defibrillators." BioMedical Engineering OnLine 4.60 (2005): 1-15

[13] Tang, Wanchun, et al. "A comparison of biphasic and monophasic waveform defibrillation after prolonged ventricular fibrillation." CHEST Journal 120.3 (2001): 948-954.

[14] PhysioNet. “How to Use the PhysioBank ATM”. http://physionet.org/cgi-bin/atm/ATM

[15] IEC 62304 - Medical Device Software - Software Life Cycle Process, Tech. Rep., 2006.

[16] ISO 14971 - Medical Devices - Application of risk management to medical devices, ISO Tech. Rep., 2007.

[17] Antonino, Pablo; Trapp, Mario; Barbosa, Paulo; Sousa, Luana . The Parameterized Safety Requirements Templates. In: Proceedings of 8th ICSE International Symposium on Software and Systems Traceability, Firenze, Italy, 2015.

[2] lifemed.com.br