Development of an Educational Alarm System: Study of IEC 60601-1-8:2022 - Alarm Systems in Electromedical Equipments

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This article addresses the development of an educational alarm center applied to the study of ABNT NBR IEC 60601-1-8:2022 - general guidelines, tests and guidelines for alarm system requirements in electrical medical equipment and electrical medical systems. The project covers prioritization conditions, frequency, and aspects related to the functional structure of a prototype. The process was divided into three stages: general and specific research, schematic and organizational assembly, and circuit validations. The perspective is to develop it with the performance characteristics of an electromedical device.

Keywords: Alarm Center. Automatic. Electromedical Equipment. Alarm Issuing System.

Introduction

The advancement of technologies applied to the healthcare field has significantly transformed how services related to this sector are delivered. With this advancement, alarms are crucial in assisting healthcare professionals in monitoring patients. However, in many cases, there is an observed saturation in the number of alarms present in hospital beds, which can lead to desensitization of the hospital staff, potentially resulting in dangerous situations. This scenario emphasizes the need for the study of alarms and their specific characteristics.

In Brazil, all technologies encompassing these devices are based on the provisions of NBR IEC 60601-1-8:2022, which standardizes Alarm Systems in electromagnetic equipment and systems, determining their aspects.

There is no literature similar to the educational alarm kit device, both in concept and in purpose. Consequently, educational projects that prepare students in the biomedical and electromedical sectors for the characteristics of alarms in hospital equipment are limited and need to be more widely disseminated.

This article aims to show the elements that make up the regulatory framework related to alarm generation and instruct students on standardization in electromedical equipment. The prototype aims to facilitate the student's teaching and learning process through interaction with the device. According to Pagel and colleagues [6], the student's interaction with equipment during practical classes enables a better understanding of the subject of study, allowing them to establish cognitive connections inherent to their environment. With the kit, students can understand the functional logic structure implemented in a hospital alarm device. It is important to emphasize that understanding this operation also means comprehending the regulatory structure presented by ABNT – Associação Brasileira de Normas Técnicas. Finally, the inspiration for this development was derived from the many applications of educational robotics concepts as a tool for technology integration [1,2].

Materials and Methods

This project developed a prototype that should indicate alarm levels by NBR IEC 60601-1-8:2022 for each type of urgency (low, medium, and high). The project was divided into three stages:

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a) Planning: Researching the standard and the components and characteristics of the electronic circuit and software.

b) Schematic and Organizational: The circuit diagram was constructed using the KiCad software. Subsequently, the circuit was assembled with the appropriate electronic components. The PlatformIO platform, an extension of the Visual Studio Code source code editor, was used to upload the algorithm.

c) Testing and Validation: Functional tests were performed on the proposed circuit. Additionally, we observed whether the alarm signal was by NBR IEC 60601-1-8:2022.

Definitions

The Educational Kit corresponds to a benchtop prototype developed with materials applied to robotics. It is divided into three parts: the first contains the normative parameter, followed by the logical operating principle, the sequence of operation, and finally, the electronic circuit with the programming code. Firstly, the criteria applied to the system's operation correspond to specific topics of the NBR IEC 60601-1-8:2022 standard. The features were incorporated by analyzing the sound emission, the text on the screen, and the emitted color. The most important topics of the ABNT NBR IEC 60601-1-8 standard for the scope of the project were the 6.1.2, which determines the alarm conditions and priority assignments according to the patient's needs; the 6.3.2.2, which characterizes visual alarm signals for high, medium, and low priority; and the 6.3.3, which describes auditory alarm signals, their frequency, and activation time according to priority conditions. Additionally, the standard includes the pulse frequency (150 to 1000 Hz) in its annexes and melodies to avoid confusion between alarms (Annex F of the NBR IEC 60601-1-8:2022 standard). The standard also stipulates that in the event of a power supply failure, the system may generate an auditory alarm that does not comply with the requirements of Annex F. Table 1 detailed all applied topics.

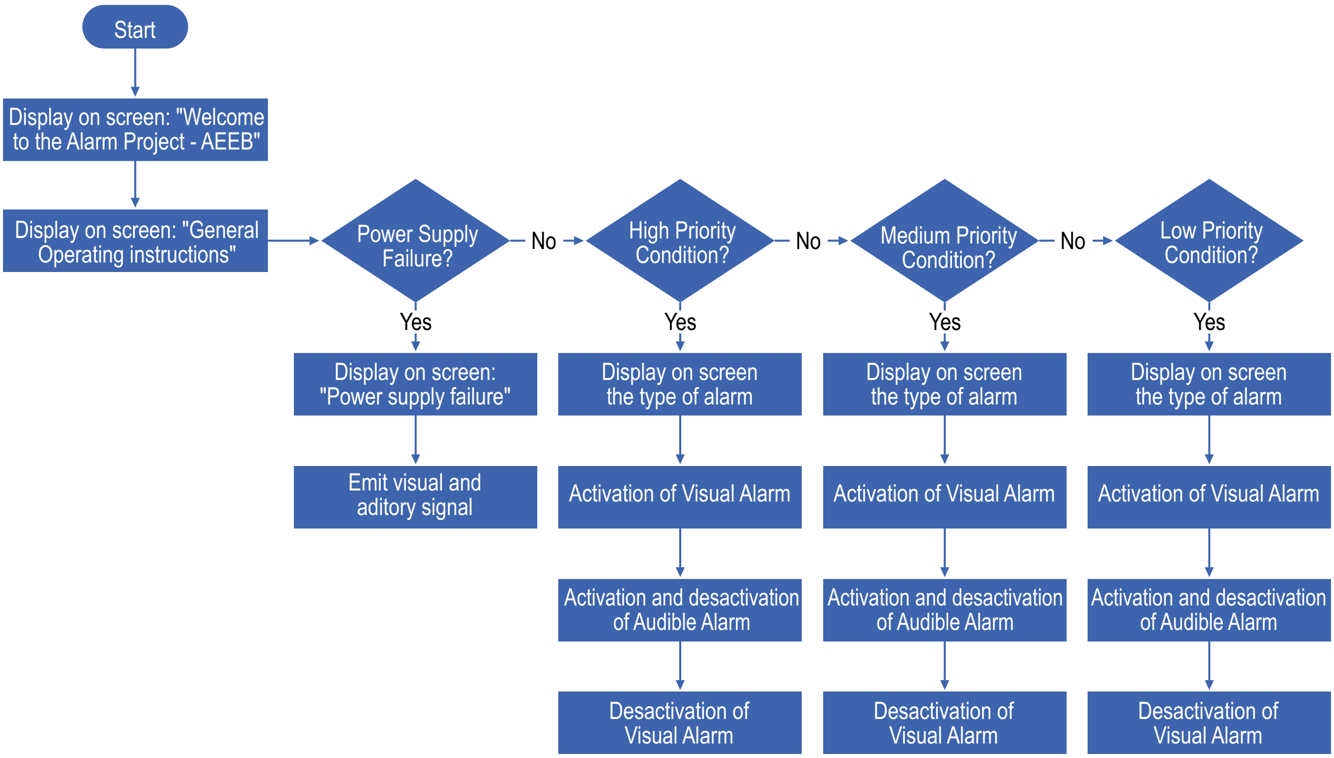
Based on these topics, we can establish the logical operating principle (Figure 1), and the programming structure.

Table 1. Topics of Standard 60601-1-8:2022.

Specifications	High priority	Medium priority	Low priority
Color	Red	Yellow	Cyan or Yellow
Frequency	1.4 Hz at 2.8 Hz	0.4 Hz at 0.8 Hz	Constant
Number of save pulses	10	3	1 or 2
Pulse interval (milliseconds)	Between 12 and 50	Between 50 and 100	Between 50 and 100
Interval between saves (milliseconds)	Between 2.5 and 15	Between 2.5 and 30	>15 or without repetition
Pulse difference	10 dB	10 dB	10 dB
Effective pulse duration (milliseconds)	Between 25 and 75	Between 90 and 200	Between 400 and 600
Melodic condition (Cardiac cause)	C E G, Pause, G C*	C E G	E C

*One octave higher.

Figure 1. Operating logic.



The programming structure is available on the drive and can be accessed through a link [3].

The alarm center should display text messages to the user on the screen based on the operator's action by pressing the buttons, enabling the demonstration. A sequence of decisions determines the priority conditions and the alarm emission involved, and the operation time of the devices is applied to these decisions according to the type of priority. For the LEDs, it is between a constant regime and a period of 1.25 seconds, and for the Buzzer, it is an interval between 12 milliseconds and 30 seconds. We have to consider the pulse time (pulse the emission of a frequency), the interval between pulses, and the interval between bursts (being the bursts a sequence of repetitions) for auditory emissions.

Figure 2 reveals the circuit's sequence of operation. The screen displays the information of the command coming from the operator through the button press, and, after that, the system emits the alarms.

Figure 3 presents the electronic circuit and Table 2 shows the devices of the educational alarm.

Results and Discussion

In the benchtop prototype, powered via USB, all four emission formats were achieved: Power-on failure, low priority condition, medium priority condition, and high priority condition (Figures 4 and 5). For each concept, the emission had two essential characteristics: the frequency and activation period. Despite the standard not specifying the frequency of the emitter set, in the case of Power-on failure, we introduced the frequency. The emitted melody sequence is one octave higher C, C minor, and C minor, with the LEDs having a constant frequency.

Moreover, an amplifier circuit (transistor, forward-biased diode, 100Ω resistor) was adopted in the project to increase the intensity of the sound emission from the buzzer (Figure 3) to improve the system' functioning. The most challenging factors in the tests' validation process were:

Figure 2. Sequence of operation.

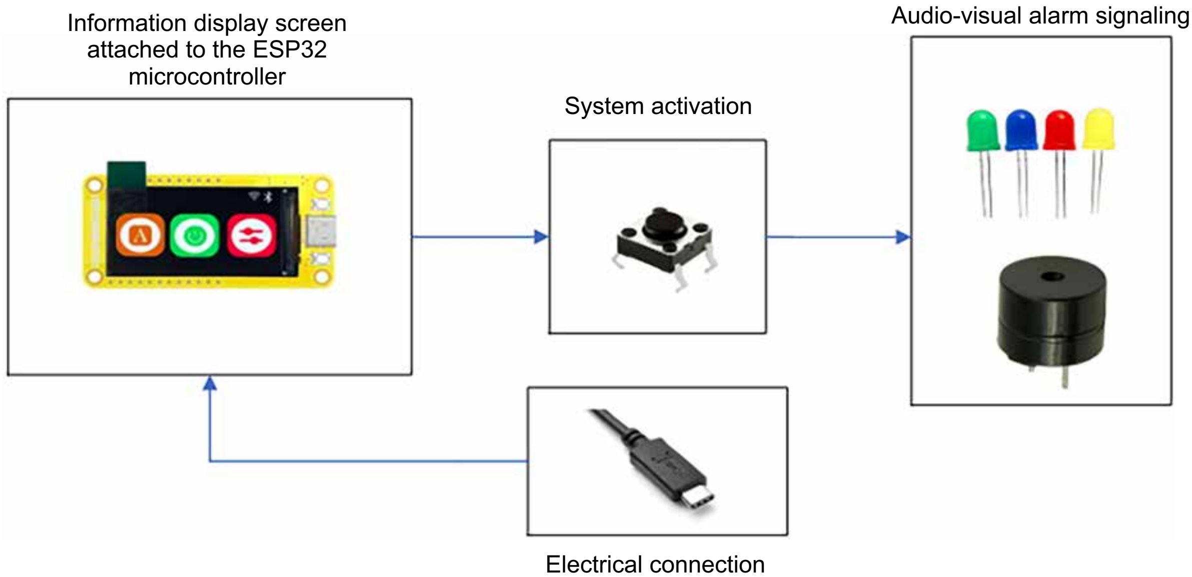


Table 2. Devices of the educational alarm center.

Device	Quantity	Functionality	Specificity
LED	2	Visual emission of light	Colors: red and yellow
Resistors	6	Apply electrical resistance	470Ω, 100Ω e 1000Ω
Button	3	Circuit actuator	Push button
Buzzer	1	Audio emission at specific frequencies	5-volt passive buzzer
Microcontroller	1	Visual information display	ESP32-S3-R8N16
Protoboard	1	Circuit construction and activation board	Model: ZY-204
Transistor	1	Amplifier	Model: BC546
Diode	1	Conduct electric current	Model: 1N4148
Jumpers	16	Perform a connection	Use of many colors

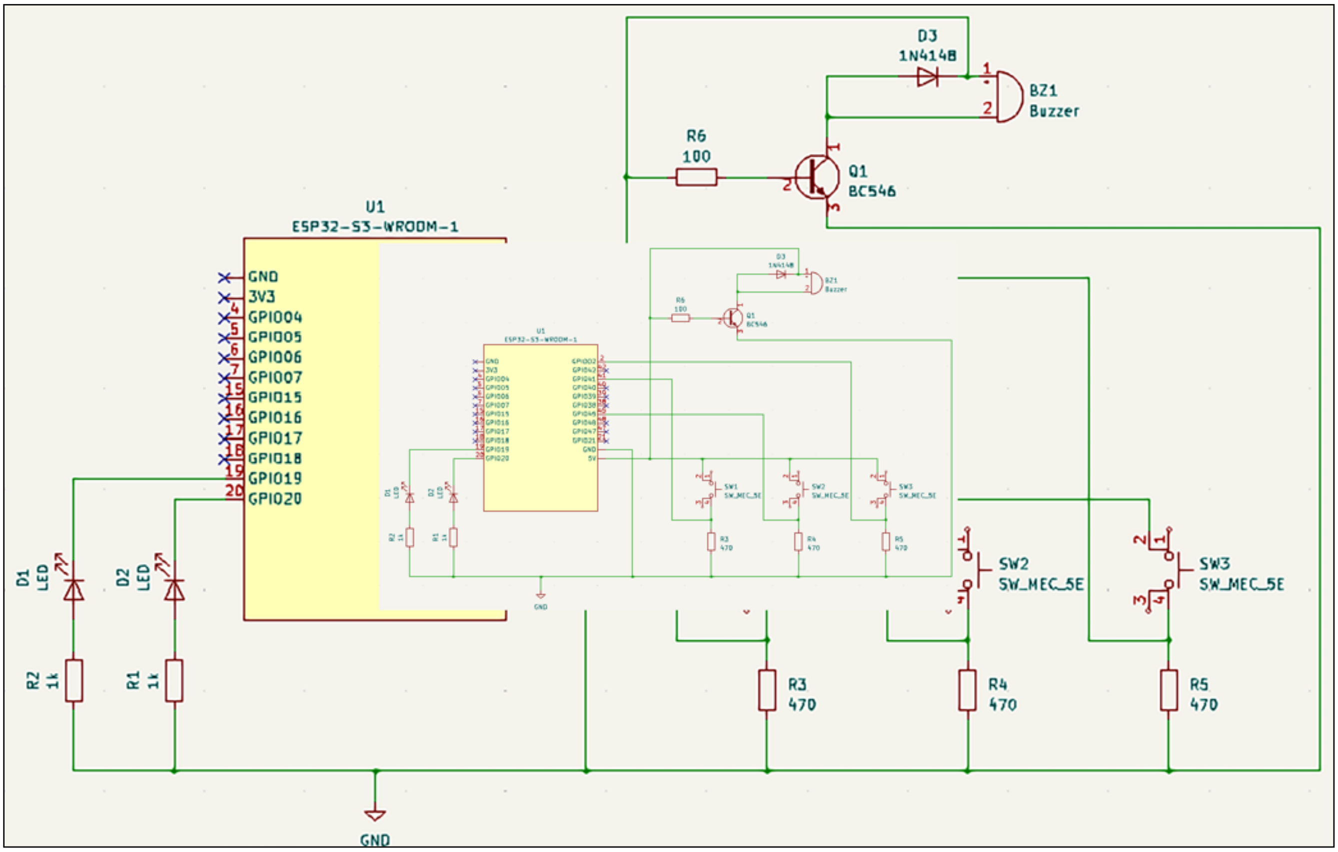
- The perception of the difference between the active and passive buzzers, i.e., the operation based on the frequency determined by the programmer, which the passive buzzer has, and the operation of a single frequency, not determined and already associated with the device, which the active buzzer has.

- The activation of the LEDs while there was the sound activation, meaning to start the LED and sound almost at equivalent moments.

Initially, the entire structure in this aspect was placed sequentially. However, the possibility of using time timers in the system became apparent after in-depth analysis. Thus, using the built-in timer of the microcontroller system, through two timers for medium and high-priority conditions, it was possible to create an impressive performance context.

In general, the proposed concept was achieved, the entire structure was tested and validated,

Figure 3. Electronic circuit of the alarm center.



and a comparison of emission with the device [4] associated with the equipment [5] in the Biomedical Equipment Engineering Area at SENAI CIMATEC was conducted. Both systems observed the following signal characteristics: comparison of activation time, synchrony, and sound and LED frequencies.

Conclusion

This article describes developing an electronic alarm emission project inspired by normative requirements. The main characteristic is that it enables immersion in the standard NBR IEC 60601-1-8:2022 and thus creates a context of practical learning for students in the medical field. For the following steps, the educational alarm system could have several applications, such as using an SD module to add images to the screen, measuring and comparing the emitted frequency with another device, manufacturing printed circuit boards, incorporating and parameterizing a medical signal, and building an integrated system with an alarm communicator.

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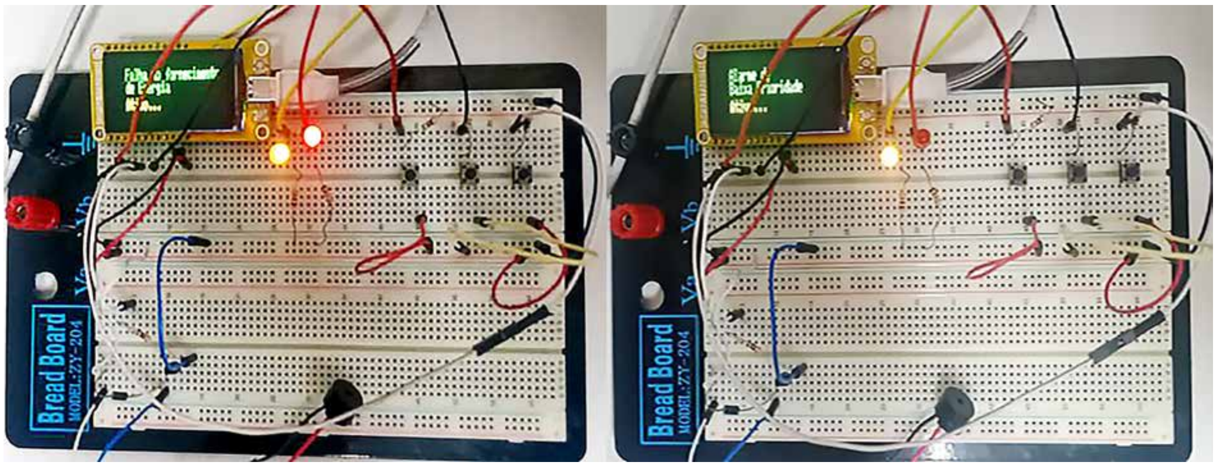
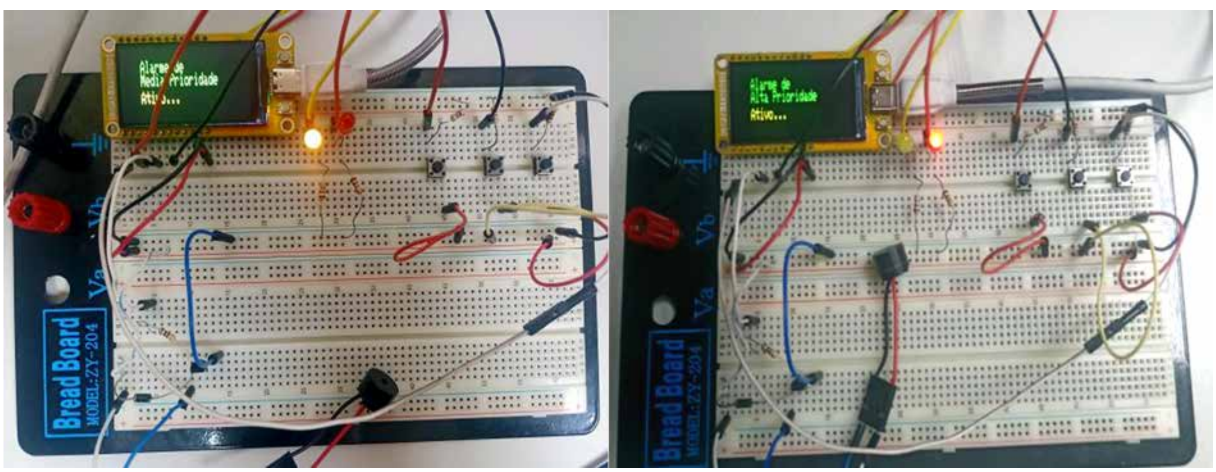
Figure 4. Power supply failure (a) and low priority condition (b).



(a) (b)

Figure 5. Medium priority condition (a) and high priority condition (b).



(a) (b)

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