UNIVERSIDAD POLITÉCNICA DE MADRID

ESCUELA TÉCNICA SUPERIOR
DE INGENIEROS DE TELECOMUNICACIÓN

MASTER EN INGENIERÍA BIOMÉDICA

MASTER THESIS

DESIGN AND IMPLEMENTATION OF A BLEEDING TRAUMA MODULE FOR CLINICAL SIMULATION

Beatriz Martín Calpena

2019

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Tutor: Blanca Larraga García

Acknowledgements

Para empezar, me gustaría agradecer al Hospital Universitario de La Paz su entrega y dedicación durante estos meses. Agradecer en especial a Javier por el apoyo y la ayuda constante.

Gracias a mis tutores y compañeros del laboratorio por haberme guiado y apoyado en la elaboración de este Trabajo de Fin de Master.

Por último, me gustaría dar las gracias a mi familia y amigos, cuyo apoyo ha sido imprescindible durante este año.

Resumen

El traumatismo hemorrágico es una de las mayores causas de muerte en el mundo, lo que supone una gran importancia la práctica de protocolos de actuación frente a estas situaciones por parte de los equipos médicos. Para ello, se reproducen escenarios de simulación clínica donde los equipos médicos pueden practicar estas técnicas.

La simulación clínica es una técnica de aprendizaje utilizada para la formación de equipos médicos con el objetivo de adquirir conocimientos y habilidades sobre el caso que se pretende simular. Es por ello que, un módulo de sangrado para la simulación clínica, puede ser un complemento útil para la asimilación de los protocolos de actuación frente a casos en los que el paciente sufra un traumatismo hemorrágico.

En este Trabajo Fin de Máster se ha desarrollado un simulador capaz de reproducir diferentes escenarios de trauma hemorrágico. Los escenarios a configurar se caracterizan por el tipo de sangrado (arterial y/o venoso) y por el tipo de vaso sanguíneo según su localización en el cuerpo (central o periférico). Para el control y manejo del simulador, se ha creado una interfaz web que permite el acceso a la configuracion de este tipo de escenarios clínicos. Esto permite un mejor control sobre el simulador de forma automática y más cómoda que los simuladores utilizados actualmente en el Hospital Universitario de La Paz.

Así mismo, para llevar a cabo este trabajo, se ha realizado un estudio del trauma de sangrado con el objetivo de conocer los diferentes escenarios posibles y los protocolos existentes para tratar una lesión de traumatismo hemorrágico.

Este Trabajo Fin de Máster se ha realizado con la colaboración del Centro Avanzado de Simulación y Entrenamiento Clínico del Hospital Universitario La Paz, donde se ha realizado la validación clínica del trabajo presentado.

Abstract

Bleeding trauma is one of the leading causes of death in the world; therefore, protocols for dealing with these situations is of great importance for medical teams. To this purpose, clinicians can practice these techniques using clinical simulation scenarios.

Clinical simulation is a learning technique used for training medical teams with the aim of acquiring knowledge and skills about the simulated case. For this reason, a bleeding module for clinical simulation can be a useful complement for the assimilation of action protocols in cases in which a patient suffers a bleeding trauma.

A simulator capable of reproducing different bleeding trauma scenarios has been developed in this Master Thesis. The configuration of bleeding scenarios is characterized by the type of bleeding (arterial and/or venous) and by the type of blood vessel according to its location in the body (central or peripheral). For controlling and handling the simulator, a web interface has been developed which allows access to the configuration of this type of clinical scenarios. The web interface allows a better control over the simulator in an automatic and more comfortable way than the simulators currently used at the Hospital Universitario La Paz. .

Moreover, to achieve this objective, a study of bleeding trauma has been carried out with the aim of identifying the different possible scenarios and the existing protocols for treating a hemorrhagic trauma injury.

This Master Thesis has been done in collaboration with the Advanced Clinical Training and Simulation Centre of the Hospital Universitario La Paz, where the clinical validation of the solution presented has been carried out.

KEYWORDS: SIMULATION, BLEEDING TRAUMA, SIMULATOR, BLOOD VESSEL, WEB INTERFACE.

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List of abbreviations

HULP: Hospital Universitario La Paz.

ICU: Intensive Care Unit.

bpm: Beats per minute.

HR: Heart Rate.

SV: Stroke Volume.

EDV: End diastolic volume.

ESV: End systolic volume.

CO: Cardiac Output.

AIS: Abbreviated Injury Scale

CNS: Central Nervous System

Chapter 1

Introduction

This Master Thesis has been done in collaboration with the Hospital Universitario La Paz (HULP), in particular with the Advanced Clinical Training and Simulation Center. This Project has been proposed in order to continue with the development of bleeding trauma module for clinical simulation.

This work has been supported by the medical and technical teams of the simulation center of the HULP and a clinical study of bleeding trauma has been done with specialist of Intensive Care Unit (ICU).

1.1 Cardiovascular system

The cardiovascular system is composed of the heart, blood vessels and blood. It transports approximately 5 liters of blood around the body and is responsible for the nutrients, oxygen, carbon dioxide and other body waste removal distribution to the body cells.

In order to understand the functioning of the cardiovascular system, its principal elements must be defined:

- The **heart**: works as a mechanical pump distributing blood through the blood vessels to the whole body. It regulates the blood flow depending on the information received by the rest of the organism in terms of oxygen and nutrients.

  The heart is composed of four chambers: two auricles, placed at the top of the heart, and two ventricles, placed at the bottom of it. The heart conducts the blood between the chambers so it follows a cycle, getting oxygenated when passing through the lungs and exchanging oxygen and nutrients when it goes to the different organs of the body [5].

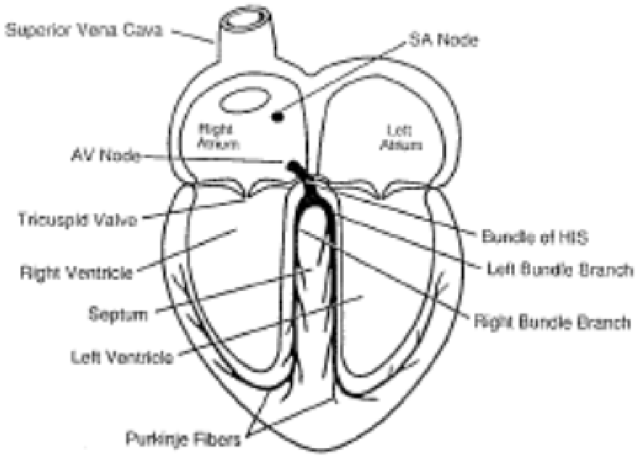

Figure 1.1: Structure of the heart [21].

The movement of heart's muscles is produced due to the electrical signal generated by an action potential causing depolarization of the skeletal muscle cells. Different action potentials produce different contractions in the heart, providing a cycle movement. The connection between cardiac muscle cells allows the heart to module the heart rate [21].

Heart contractions are classified in two types: systole and diastole. The systolic contraction represents the heart contraction in which the blood is pumped to the blood vessels, while the diastolic contraction is the relaxation phase where the blood returns to the heart to start the cycle again.

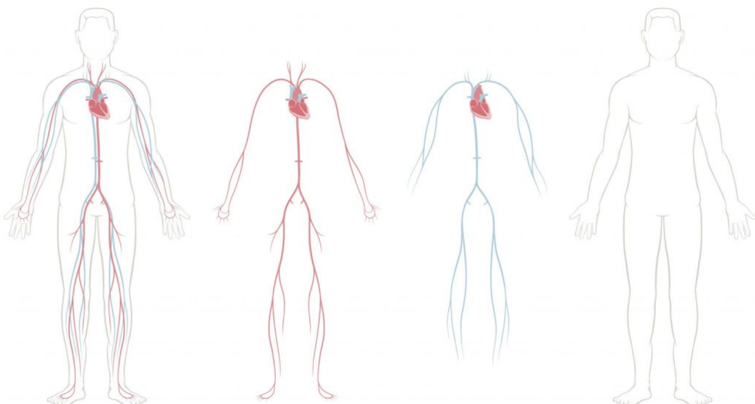

Figure 1.2: Cardiovascular system[12].

- The **blood vessels**: Elastic and muscular tubes responsible for conducting the blood to the different organs of the human body. The three main types of vessels are:
  - *Arteries*: Arteries transport the blood from the heart, carrying oxygen and nutrients, to all tissues and organs of the body, except for the pulmonary

artery. This artery carries the blood with carbon dioxide to the heart to be removed. The blood flow in this type of vessels is pulsating.

  - *Veins*: These vessels are responsible for carrying blood from the organs and tissues to the heart, except for the pulmonary vein which delivers blood containing oxygen and nutrients. The blood flow in these vessels is a continuous flow and it tends to be darker due to the lower level of oxygen carried.

  - *Capillaries*: Capillaries are thin vessels which connect arteries and veins. They are responsible for the exchange of oxygen and nutrients.

- The **blood**: The blood is a body fluid that circulates through the vessels. It is composed by blood plasma and the form elements: erythrocytes, leukocytes and platelets. Blood does not only transport nutrients and oxygen to organs and tissues but also waste removal resulting from the cell metabolism and hormones [5].

For a better understanding of the blood flow and its characteristics and functioning, some cardiovascular terminology will be detailed as follows.

The blood flow circulating around each part of the body depends on the body's physical needs by means of oxygen, carbon dioxide and nutrients. The heart normally delivers 5 liters of blood flow per minute, which allows the blood to reach every part of the body providing oxygen and needed nutrients.

The speed of the pumping heart is represented in the **heart rate** (HR), which measures the number of beats per minute (bpm). The rhythm is represented in bpm and it regularly takes values of 60-100 bpm as per Figure 1.3. These values are shown in the electrocardiogram (ECG) and are controlled by medical teams.

Figure 1.3: Normal ECG [28].

Values above 100 bpm at rest, as shown in Figure 1.4, are considered tachycardia while values below 60 bpm, as shown in Figure 1.5, are considered bradycardia.

Figure 1.4: Tachycardia ECG[28].

Figure 1.5: Bradycardia ECG [28].

The heart rate at rest has a regular pattern so, when it changes to irregular rates, it is referred as an arrhythmia (see Figure 1.6).

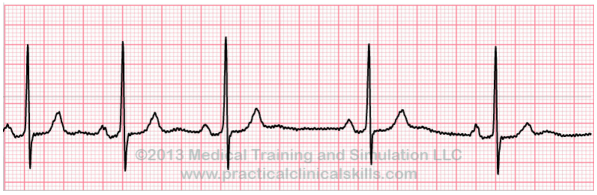

Figure 1.6: Arrhythmia ECG [28].

Other parameters such as the **stroke volume** (SV) represents the volume of blood pumped by the left ventricle of the heart per beat. It is the difference between end diastolic volume (EDV) and end systolic volume (ESV). The EDV is the blood volume resulting from filling the ventricles in the diastolic contraction, while the ESV is the one obtained in the auricles at the end of the systole. The stroke volume value depends on the weight and age of the person but it normally takes values of 60-100mL [24].

$$SV_{[mL]} = EDV_{[mL]} - ESV_{[mL]} \tag{1.1}$$

The HR and the SV determine an important parameter in the cardiovascular field called the **cardiac output** (CO). This term describes the volume of the blood flow pumped by the heart per unit time. Normal values for a healthy person are between 5 and 8L [24].

$$CO_{[L/min]} = SV_{[L/beat]} \times HR_{[beats/min]} \tag{1.2}$$

1.2 Clinical simulation

Clinical simulation is a learning tool currently under an important development and it is starting to bring important results within the health care sector. Clinical simulation training requires incorporating not only theoretical but also procedural knowledge which supports a more complete learning process. Complementing the theoretical knowledge with simulation exercises to acquire a better performance on the daily tasks of the medical teams, is one of the most important advantages of clinical simulation [11].

It is demonstrated that clinical simulation contributes to the development of trainees confidence and knowledge integration [10]. Using clinical training exercises, simulators help to improve the skills and techniques of different medical scenarios. Nevertheless, these exercises are not only practiced to acquire technical skills but also to improve personal skills such as self-control, self-confidence and communication skills that can be very important and decisive for the patient's treatment.

Several clinical centers admits that clinical simulation is a useful tool to practise and improve medical skills. According to the Clinical Nurse Transition Program director: "Simulation training provides medical teams opportunities to promote critical thinking and leadership skills through simulated medical patients" [16].

In every practical simulation case, a target group, the skills to practise and the level of feedback required in the session must be defined. For a better involvement of the medical teams, real cases are simulated so that they could experience and learn how to solve and anticipate to problems that may arise during their daily work.

In clinical simulation, high fidelity mannequins are used to reproduce training scenarios with the focus on specific cases which need a feedback from the patient. Moreover, low fidelity mannequins are used for those cases in which a specific feedback of the patient is not needed and it is only used for practising some medical techniques.

1.3 State of the art

A bleeding trauma module in clinical simulation consists of an electromechanical device based on the structure and functions performed by the circulatory system. It is designed to assist on the creation of bleeding trauma clinical simulation scenarios and to support trainees to have a more realistic vision about the simulated case.

As new technologies are developed, simulation expands its features and more complex systems are implemented to make a simulator as complete as possible. Starting from a mechanical element to one that acquires electronics, simulators are improving to a more sophisticated and automatic system.

Figure 1.7: Clinical training in military [16].

Due to the progress in clinical simulators, some hospital areas such as traumatology and burn treatment units which involve circulatory dysfunctions, demand bleeding trauma modules to support them to reproduce hemorrhagic real cases. The implementation of bleeding trauma modules to simulators supports the need to create new cases involving one of the most common cases in hospitals, trauma injuries.

Clinical training is used in different environments, not only at hospitals but also for other teams who need health care services in a specific moment such as military or security services as shown in Figure 1.7. These teams receive clinical trauma injury training to carry out their professional jobs and to be able to attend wounded patients in case of any medical urgency.

For non hospital cases, clinical simulation is a good opportunity to prepare themselves for an experience they might have in the future and to avoid feeling overwhelmed in the field due to their practical sessions. Therefore, the focus to learn different roles will help them to get through this situations easily [8].

On the other hand, bleeding trauma modules are used by medical teams to improve their skills in their daily work. There are many possible use cases of bleeding trauma simulation that can be developed for clinical training and not all of them would take place at hospitals but also during pre-hospital situations such as traffic accidents, falls, injury because of weapons, etc.

Bleeding trauma simulators can be classified depending on the skills to practise in the simulation and the feedback wanted from the patient:

- **High fidelity simulators:** Among the most complete bleeding trauma simulators, SimMan 3G Trauma from Laerdal stands out. It was designed to train military and civil emergency medical personnel in trauma situations, including hemorrhage.

  This high fidelity simulator is suitable for training in the assessment of trauma emergencies. It is capable of simulating interventions such as hemorrhage control and airway management, which are essential for patient control in cases of bleeding trauma [15].

  The SimMan 3G Trauma, as shown in Figure 1.8, has technological features suitable for its handling in wireless form. Due to this communication technology, it is easy to control and extends its uses to any case of trauma simulation. It combines cardiac and circulation modules among others; therefore, the simulation can be more realistic.

Figure 1.8: SimMan 3G Trauma simulator [15].

- **Low fidelity simulators:** These simulators are designed to improve the bleeding control technique and learn how to use the necessary medical tools and devices. They can be used as clinical simulators but are not as real as the previous mentioned. Several bleeding trauma modules are already available in the medical simulator industry. Some of them are more advanced than others but each one of them is valid for specific trauma cases [1].

Figure 1.9: Soldier Leg Bleeding Simulator [27].

Two types of low fidelity simulators can be classified on: Simulators integrated in parts of the human body (extremities, thorax, head) and module simulators that only represent the circulatory system ducts. The differences between them are due to the objectives of practical skills.

- Integrated: Integrated simulators, as shown in Figure 1.9, are very suitable for training sessions prepared to improve technical skills of controlling bleeding and trauma contusion [27].
- Module: Module simulators, which are not implemented in any part of the body, are capable of suiting in any type of simulation case. This ability is due to its flexibility and simple design.

Figure 1.10: Individual bleeding trauma module [26].

Module simulators, as shown in Figure 1.10, can be used with real persons who simulate a patient. In this type of clinical sessions, the trainee will be able to communicate with the patient and receive some feedback about the medical practice.

Figure 1.11: PROMPT Flex bleeding module [17].

Most of these simulators, as shown in Figure 1.11, usually tend to have a fluid tank that serves as a blood flow supply. A set of flexible tubes are incorporated in the design of these simulators. Due to this configuration, the tubes can simulate blood vessels and their flexibility enables the adaptation to any type of simulation.

Module simulators are used in clinical simulation centers due to its adaptability to any type of simulator. Some of the disadvantages of these simulators are the mechanism of manual operation and the lack of realism in the scenarios since an auxiliary person is needed to generate the bleeding pulse.

As a conclusion about the available bleeding trauma simulators, depending on the simulation case needed to practise, there are three options to take into account:

- High fidelity simulators: They are used in those cases which a feedback of the patient is needed, therefore, it gives a more complete simulation case.
- Low fidelity simulators: These simulators are used in hemorrhagic trauma scenarios when a high level of feedback is not needed. Integrated simulators are used to practice technical skills, and the modules to practice the treatment with the patient.

  Most of the existing simulators does not include an interface to its control or have a manual operating mechanism to generate the bleeding pulse, removing realism from bleeding scenarios.

1.4 Project scope and objectives

The simulation center of HULP works on the creation of new simulation courses using different simulators which help them to make clinical training sessions more realistic.

Therefore, a bleeding trauma module simulator will be developed with the following aspects:

- **Design**: The simulator has to be portable and wearable, to be able to use it for different trauma scenarios. The simulator has to be flexible to be able to adapt it to different human body surfaces. Moreover, its size should be reduced in order to enhance its portability and manoeuvrability.
- **Functionality**: The bleeding action is performed due to a complex system of the blood vessels. The module should be able to reproduce all types of bleeding scenarios taking into account the type of vessel and the location in the human body.
- **Connectivity**: The connection between instructor and bleeding trauma module should be intuitive, wireless and constant. A user friendly interface will support the whole training process.
- **Adaptability**: The simulator should be able to reproduce different groups of patients, such as children or adults, men or women. The module simulator is prepared also to deal with other simulators and to be integrated on other high fidelity simulators improving them.

In order to fulfill these characteristics, an electromechanical device will be developed for simulating different scenarios of bleeding trauma.

The electronic circuit will be able to reproduce, by means of a pumping system, the arterial and venous bleeding of the human body as well as the measurement of the pressure exerted by the trainee when controlling the hemorrhage.

For controlling and handling the system, an application will be created. Moreover, this application will allow the access to the configuration characteristics of the bleeding trauma module.

1.5 Document Layout

The manuscript has been structured in six different sections.

Chapter 2 shows an introduction to trauma focusing on bleeding trauma injury. In this section, different types of bleeding trauma, as well as its classification in severity levels and protocols to follow, will be studied. Moreover, the three predefined bleeding trauma scenarios available in the web interface will be presented as an example of the different possible simulator scenarios.

Chapter 3 presents the hardware design of the simulator. First of all, a description of the design requirements will be presented and then, the complete hardware design will be explained. The hardware design has been presented in three different parts: the electronic design, the mechanical design and the electronic control design. In each part, details about the hardware elements and its specifications will be shown.

Chapter 4 refers to the software design. The software requirements for the development of the web interface and the simulator will be described, as well as the design of the whole project. The software design has been organized in three different sections: the web development, the communication between the web and the simulator, and the simulator software.

Chapter 5 shows the clinical validation and the results of the project with regard to the proposal. The results of the bleeding trauma simulator and the simulation scenarios are explained based on some simulation examples.The results of the clinical validation carried out in the Hospital Universitario La Paz are presented.

Chapter 6 presents the conclusions of the final project and future developments. In this Chapter, an evaluation of the simulator has been done based on the objectives and the hospital requirements.

Chapter 2

Bleeding trauma

2.1 Introduction

Trauma is defined as a bodily injury caused by an external agent which produces not only damage of the dermal surface and tissues behind it, but also malfunctioning damage.

The skin is the largest organ in the human body and it plays an important role of protection against infections. Other important functions of the skin are: regulation of blood circulation, sensory receptor of touch, pressure and temperature, among others. It is highly vascularized and has several receptors which perceive external changes. The skin has different thickness depending on its location and it is also affected by some parameters such as age, health conditions and gender. Due to this reason, a rupture of the skin surface can be dangerous for the normal functioning of the organism, producing malfunctions and infections which could lead to other pathologies [31].

Trauma injury can affect to several organs and tissues. Its medical attendance level depends on the Abbreviated Injury Scale (AIS), which classifies trauma injury as per Table 2.1.

AIS	**Level**
AIS 1	Minor
AIS 2	Moderate
AIS 3	Serious
AIS 4	Severe
AIS 5	Critical
AIS 6	Maximal (currently untreatable)

Table 2.1: AIS scale [3].

The AIS scale also provides a standardized classification of injuries by its severity and location. Depending on the body region affected, patients are treated according to the following priority levels:

Priority	Body region
1	Head/Neck
2	Face
3	Thorax
4	Abdomen/Pelvis
5	Extremities
6	External

Table 2.2: Body region severity scale [14].

According to the National Institute Trauma of Texas (EEUU), as shown in Figure 2.1, trauma injury is one of the leading causes of death in the world (47% of deaths). This represents a high number of patients per year suffering any type of trauma and doctors are concerned about the increase of it [20].

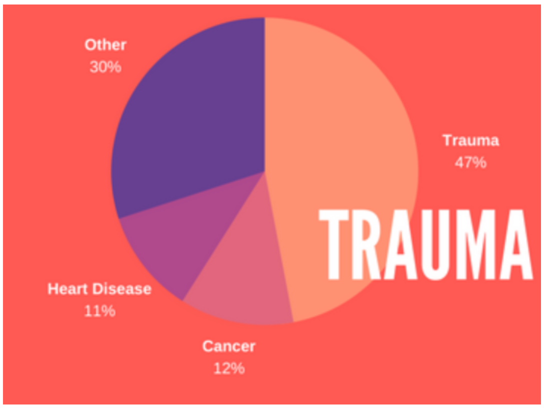

Figure 2.1: Trauma deaths statistics [20].

In every trauma injury, the cardiovascular system is nearly always affected; therefore, this may cause more complex problems in organs or tissues due to the bleeding trauma injury. Bleeding trauma injury involves physical damage, which is identified by a loss of blood and, consequently, a change of its properties and composition. In case of a deep injury, it can affect several organs of the body or bones, as well as it may generate complications which put the patient's life at risk.

One of the biggest risks of having a bleeding trauma injury is the massive bleeding which, as explained above, can cause major damage in the organism. This massive bleeding is called hemorrhagic shock.

2.2 Hemorrhagic shock

The hemorrhagic shock is one of the potentially preventable deaths that affect to all population. It can be produced by several events such as traffic accidents, violence, homicide and suicide. It is characterized by a massive extravascular loss of blood, which decreases the blood volume and affects not only to the hemodynamic stability but also to organ damage and, in the worst case, to a multiorgan failure[29].

At cellular level, the oxygen delivered by the blood decreases disturbing the normal aerobic metabolism of the organism. The aerobic metabolism, in the presence of oxygen, generates energy through the combustion of carbohydrates, fats and amino acids [30]. As a result of different changes, the cellular homeostasis, which regulates the physical and chemical conditions, fails leading to a cell death. On the other hand, tissues could have been affected by the oxygen deficiency and, therefore, it could produce a multiorgan failure which is difficult to recover [13].

During a hemorrhagic shock, the patient starts loosing blood volume and, therefore, the heart rate starts increasing due to the low level of oxygen delivered to the organism. The breathing rate also increases. The lack of oxygen in the metabolism generates changes in the perfusion and also in the central nervous system. All theses symptoms appears gradually as the exposure time to the hemorrhagic shock increases. The state of trauma patients can be different depending on the severity and location of the injury, using as a reference the AIS trauma scale. As the cardiovascular system interferes with all important functions of the body, it is crucial to evaluate the patient conditions.

Hemorrhagic shock injuries can be classified in four different levels, as shown in Table 2.3, taking into account the parameters which reveals the severity of the injury, such as the volume of blood loss, the heart rate and other symptoms related with the Central Nervous System (CNS).

Parameters	**Level 1**	**Level 2**	**Level 3**	**Level 4**
Blood loss (mL)	750	750-1500	1500-2000	>2000
Blood volume loss (%)	15%	15-30%	30-40%	>40%
HR (bpm)	<100	100-120	120-140	>140
Perfusion	Normal	Paleness and coldness	Paleness, coldness, sweating	Paleness, coldness, sweating and capillary filling >3s
CNS symptoms	Normal	Anxiety	Confusion	Lethargy

Table 2.3: Levels of hemorrhagic shock [13].

It is really important the correct evaluation in order to get the best medical care for the patient recovery [6]. The main characteristics of the different levels of injury are explained below:

- **Level 1**: bleeding trauma blood loss corresponds to the amount of blood from an individual donation (15% of total blood volume),therefore, it is not a risky situation. Clinical symptoms may show a minimum tachycardia but no changes appear in the heart rate, breathing rate or in the arterial pressure.
- **Level 2**: hemorrhage patient presents clinical symptoms including tachycardia, increase of the heart rate and decrease of the arterial pressure. Some changes in the CNS may appear such as anxiety, aggressiveness, etc. These patients may require a transfusion but initially, they can be stabilized with crystalloids infusion.
- **Level 3**: hemorrhage indicates a more complicated bleeding trauma where crystalloid infusion and blood transfusion are needed. Patients present risky symptoms of tachycardia, mental changes and a decrease of the sistolic pressure.
- **Level 4**:is the most critical level in which patients need urgent attendance due to the amount of blood volume lost including blood transfusion and surgical intervention. Patients in this bleeding status feel tachycardia, low cardiac pulse pressure, paleness and sometimes, their CNS gets affected causing depression.

Bleeding trauma level provides an indication of the possible bleeding trauma situation. Depending on the gender, age and other pathologies, the bleeding trauma progress could have different consequences [6]. Details about bleeding trauma patient condition are explained below:

- **Adult patient**: In a general case of an adult patient (70kg approximately), the blood volume is the 7% of the weight. The blood volume lost will affect different depending on their weight. Moreover, the crystalloids infusion required is three times the blood volume lost.
- **Pediatric patient:** These patients present tachycardia also due to the stress of bleeding situation. They may experiment a decrease in consciousness and a clumsy reaction to pain. Blood volume represents the 8-9% of patient weight. After a correct medical checkup, a surgeon must be involved for the bleeding trauma treatment.
- **Geriatric patient**: As the heart ages, some of its functions are also lost. Most of them take clotting medication due to some pathologies such as stenosis. A correct recognition of aggressive resuscitation and monitoring needs is necessary to stabilize the patient.
- **Pregnant patient**: Bleeding trauma injuries in these patients can be produced by an external or an internal hit. Trauma severity would have an impact on

the final health conditions of the mother and its baby. These patients should be hospitalized and treated with obstetrician cares. Due to the pregnancy, cava vein is compressed, therefore, the hemorrhagic shock could bring complications.

As stated above, bleeding trauma location can be very decisive for the correct protocol and bleeding control. Depending on the blood vessel affected (artery,vein or both), the recovery will be more o less complicated, as well as the location of the vessel affected (central or peripheral).

2.3 Protocols

The reaction time in bleeding trauma cases is decisive for the patient's recovery. Medical teams must act in the shortest time to reverse the damage and try to stabilize the patient as soon as possible. In order to be effective and efficient, action protocols have been elaborated. These protocols indicate the treatment execution order to follow. The main objective of bleeding trauma protocols is to keep the bleeding trauma patient safe, as effectively as possible, in order to avoid more physiological complications. Depending on the moment in which the bleeding trauma is produced, the protocol followed is different in order to start the hemorrhagic resuscitation. Two types of situations can be distinguished: at the hospital and pre-hospital.

The main objectives of hemorrhagic resuscitation are focused on restoring the circulating blood volume and stop the bleeding. These two objectives are fulfilled by activating the management protocols of massive bleeding explained below. [29].

In case that the first care attendance is at the hospital, the protocol of fluid transfusion of extreme urgency is executed. Medical teams have to notify to the blood bank in the shortest time if a transfusion is needed. Also any other medical equipment that may be needed in case of emergency should be previously requested. In order to obtain a safe patient recovery in a bleeding trauma scenario, the following steps should be followed:

1. Recognize the hemorrhagic shock status to better prepare the hemorrhagic resuscitation.
2. Evaluate of the perfusion and physical examination.
3. Identify the causes of the hemorrhagic shock.
4. Start the reanimation, identifying, controlling the hemorrhage and replacing the blood volume lost to restore the initial conditions.
5. Identify anatomic locations and vascular entries (peripheral venous system, femoral vein, etc).

6. Use different methods to help the evaluation of the hemorrhagic shock (X-Rays exploration, abdominal ultrasounds, Computer Tomography, etc).
7. Identify any surgery needed or the relocation to the ICU for a more complete monitoring.
8. Identify additional therapies.

On the other hand, in pre-hospital attendance, the patient will be treated by the SAMUR-Civil Protection. As the scenario does not have all the hospital equipment, there would be some priorities in order to follow the protocol. The source of bleeding must be occluded as soon as possible using, at first stage, by compression, tourniquets or homeostatic vests. When the bleeding is controlled, blood should be replaced for a future normalization of hemodynamic parameters and the relocation to the hospital will be needed for further attendance [25].

In order to stabilize the patient in pre-hospital scenarios, medical teams have to follow the next steps:

1. Evaluate the patient, injury diagnosis and resuscitation measurements if necessary.
2. Evaluate the scene: risks, type of scenario, physical status, etc.
3. Estimate the severity with the AIS scale.
4. Primary evaluation and resuscitation.
5. Patient transfer to a specialized hospital unit[4].

In both cases, during blood replacement, the maintenance of the volemia (total blood volume) will be achieved with the delivery of crystalloids and colloidal solutions taking into account the clinical condition of the patient. Blood replacement helps the oxygenation of the blood and the organism. Unfortunately, this is not always available on pre-hospital attendance because of the special characteristics of blood maintenance[19].

2.4 Bleeding trauma scenarios

In bleeding trauma simulation scenarios, some simulators execute bleeding functions as well as receive feedback from the simulated patient about the hemorrhage control. In this Master Thesis, in order to have a more complete simulator with a feedback of the trainee bleeding control, information about the hemorrhage control in terms of vascular compression will be registered.

The development of this simulator and a web to control it, are to be used as a training tool in the Hospital in order to achieve a real bleeding trauma simulation scenario. The simulation will be controlled by the trainer, who configures the bleeding scenario. The configured scenario will be executed by the bleeding trauma web explained in Chapter 4.

Bleeding trauma scenarios of this developed simulator can be set up taking into account the type of vessel (arterial or venous) and the location of the blood vessel (central or peripheral).

As shown in Section 2.2, there are many possible scenarios to represent bleeding trauma cases but this project will be focused on these three specific cases:

- **Scenario 1**: This scenario will simulate an adult patient with a level 3 bleeding trauma. Vein femoral injury at the hospital.
- **Scenario 2**: A pediatric patient will be simulated. Hemorrhagic shock of level 2 with a peripheral artery injury. Extra-hospital attendance.
- **Scenario 3**: Pregnant adult woman patient with a level 3 abdominal bleeding injury. Hospital attendance. Arterial and vein bleeding.

Chapter 3

Hardware Design

3.1 Hardware design requirements

The design is an important part in the development of a simulator. It has a direct impact on the applications and functions of any clinical simulator. Simulators nowadays take into account the improvement of new technologies, such as web development or Raspberry Pi microcomputers and Arduino micro-controller, which facilitates the development of different types of projects. For this reason, the design of this bleeding trauma simulator will follow this development line. The idea of using new technologies will make it more useful and interesting in order to improve it with other features. These features can be adding more actuators and sensors which amplify its functionality, or provide more possibilities when it comes to configuration.

In order to fulfill the project objectives, the design of the bleeding trauma simulator should be:

- **Portable and wearable:** The simulator should to be used for different trauma scenarios. As explained in Section 1.3, there are different uses for the simulator depending on the skills to practice. The simulator should be able to be used in scenarios with persons and with simulators of patient.

- **Flexible:** The bleeding trauma simulator has to be adaptive to different human body surfaces. With this characteristic, the simulator should reproduce bleeding trauma scenarios in different locations such as arms, legs, abdominal.

- **Robust:** The bleeding trauma should have an automatic control in order to get a robust structure for clinical application. The automation of the bleeding action is a characteristic that no simulator has, therefore it will be a needed improvement.

- **Reduced size:** In order to enhance its portability, the simulator size has to be reduced to have a better handling of it. The structure of the simulator has to be adaptable for clinical environments so it does not disturb the trainee.

3.2 Hardware design

Two different sections have been developed for the bleeding trauma simulator, as shown in Figure 3.1: the bleeding trauma simulator itself, and the control interface. In both parts, hardware has been selected in order to fulfill the needed characteristics for the simulator. These two parts are going to be constantly connected, receiving and sending data at the same time in order to get a real-time interaction.

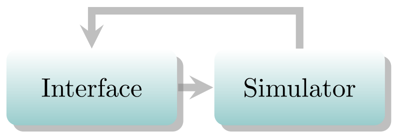

Figure 3.1: Project design.

The hardware design has been selected taking into account the characteristics of the simulator, its portability, flexibility, robustness and size. The simulator architecture is made up of three different components which are connected to each other and make the complete bleeding trauma simulator:

- **Electronic design:** The electronic design is decisive for the simulator features. It defines the type of data received and sent by the simulator. The bleeding action configured is sent to the electronic components in every simulation, allowing the representation of the bleeding trauma injury.
- **Mechanical design:** The mechanical design is composed of the materials and elements that help to build the simulator providing it with realism. This mechanical design should provide the adaptability to different scenarios.
- **Electronic control design:** This part of the simulator is in charge of its control and the connection between the interface and the bleeding trauma simulator. The web and the data transfer are managed by a microcomputer and a micro-controller.

All simulator components have been selected not only for their technical characteristics but also for the specific design requirements for medical simulation. In Sections 3.2.1, 3.2.2 and 3.2.3, all these components will be described.

3.2.1 Electronic design

The bleeding trauma simulator functions define the different electronic components that must be used for the correct design of the electronic section. As explained in Section 3.2.3, the micro-controller establishes the communication between the electronic components and the web interface. The electronic design is composed of two important sections, as shown in Figure 3.2 : One that provides the information to the trainer about the hemorrhage control (coloured in blue) and the other one that produces the bleeding trauma (coloured in red).

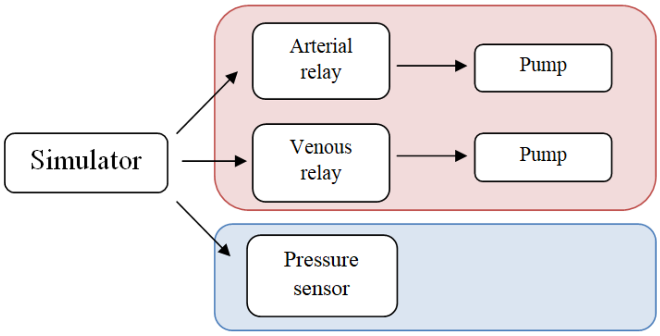

Figure 3.2: Electronic flow diagram.

The electronic components have to be compatible with the Arduino Due board and ensure that they fulfill the technical specifications necessary to be similar to the physiological aspects they represent. The electronic components of the electronic hardware design are explained in detail below:

- Pressure sensor: The pressure sensor, as shown in Figure 3.3, obtains the information about the bleeding control during the simulation. It provides a feedback from the trainee of the hemorrhage control. The pressure sensor is located under the skin (explained in Section 3.2.2) near the injury, taking the role as the pressure receptors of the real skin. The pressure sensor has an operating voltage of 5V and needs a 10KΩ as the conditioning circuit.

Figure 3.3: Pressure Sensor [9].

The pressure sensor will show the measurement in analogical lectures, which is a conversion from the voltage of the force sensor resistance. It shows values from 0 to 1023, which corresponds in volts 0 to 5V; therefore, each analogical lecture will represent 4.89V.

The simulator receives the information about the bleeding scenario to be executed. The web sends to the Arduino board the state of the bleeding trauma and activates the bleeding channels, one for the arterial and other for the venous bleeding, by the following electronic components:

- Relay: Both arterial and venous bleeding are performed through the activation of two 5V relays, as shown in Figure 3.4. They are connected to the Arduino board and get activated when the arterial or venous bleeding is selected in the web. The relay activation will be pulsating if it is an arterial bleeding and continuous if it is a venous bleeding.

Figure 3.4: 5V Relay [7].

As the operating voltage of the relays is 5V, and the Arduino Due pins activates at 3V, a conditioning circuit has been located. As shown in Figure 3.5, the conditioning circuit consists on a bipolar BJT transistor in order to regulate the current and to obtain 5V power supply for the relay activation.

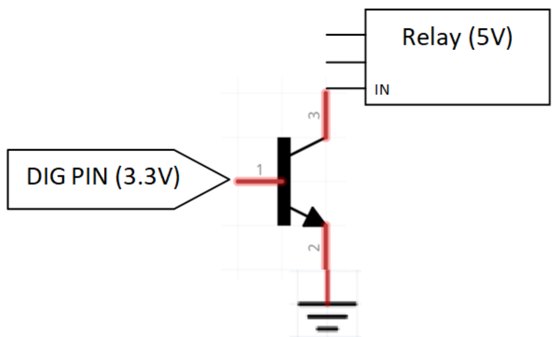

Figure 3.5: Relay conditioning circuit.

- Liquid pump: The simulator has two 5V operating voltage liquid pumps (see Figure 3.6). They perform the arterial and the venous bleeding and are connected to the relays. The arterial and venous pumps are activated when relays get activated.

Figure 3.6: Liquid pumps [18].

3.2.2 Mechanical design

Several medical design requirements have to be fulfilled in the bleeding trauma simulator development. As clinical simulators have to reproduce clinical scenarios, they have to get as closer as possible to the real medical situation. In order to get to a more realistic scenario and to get the trainees involved in the bleeding trauma scenario, the following materials and elements are set up.

- Skin band: The skin band (see Figure 3.7) is the material through which the bleeding trauma is produced. It is made of different layers composed of silicone material of different densities. It is specifically composed by three layers: a muscular layer, a fat layer and the surface layer which represents the human body skin.

Figure 3.7: Skin band.

The bleeding trauma simulator skin supports the ducts and the pressure sensor, taking into account the role of the human skin, with blood vessels and pressure receptors inside of it. The use of this silicone skin will provide realism to the simulation scenario as it will be located in any surface of a person or simulator.

- Liquid tank: In order to provide the simulator with portability, the simulator has a liquid tank, as shown in Figure 3.8, where the blood is stored. The blood is pumped through the pumps, which are inside of the tank and flows through the tubes.

Figure 3.8: Liquid tank.

The liquid tank is placed near the patient and has a small access where the tank is going to be filled when it gets empty. Moreover, the deposit size has to be small enough to be easier to transport, and big enough to be able to reproduce a clinical simulation with no need to fill in during the scenario.

- Flexible ducts: The blood circulates through two long channels during the bleeding trauma scenario. This flexible and thin ducts, as shown in Figure 3.9, represent the blood vessels and are placed inside the layers of the skin band. These plastic tubes are long enough to reach any part of the body, to be able to adapt it to any type of injury, near of far from the tank.

Figure 3.9: Flexible ducts.

3.2.3 Electronic control design

The Simulation Center of HULP uses different technologies to control their clinical simulators and many of them are controlled by an interface, which makes the clinical simulation easier.

In order to ensure a high quality connection between the web interface and the simulator, two electronic components have been used.

- **Raspberry Pi:** The microcomputer selected to be the web server for the simulator interface is the Raspberry Pi 3 Model B+, as shown in Figure 3.10. The Raspberry Pi is selected because of the possibility of using it as a web server and its wireless LAN connection, which allows an easier control.

Figure 3.10: Raspberry Pi Model 3B+ [22].

This computer board has the following specifications [23]:

– Dimensions: 82mm x 56mm x 19.5mm, 50g
– Processor: 64-bit 1.2 Ghz, four ARMv8 cores
– RAM: 1GB SDRAM
– Networking: Ethernet and wireless LAN
– Bluetooth
– Storage: Micro-SD
– GPIO: 40-pin
– Ports: HDMI, audio-video jack, 4 USB 2.0 ports, Ethernet, Camera and Display Serial Interface

The Raspberry Pi 3B+ is the web server that processes the web interface for the simulation control of the bleeding trauma scenarios. A monitor needs to be connected to it by the HDMI port in order to manage the web interface. The operating system installed in the Raspberry Pi is the Ubuntu Mate.

- **Arduino Board:** The Arduino used by the electronic control of the simulator, as shown in Figure 3.11, is the Arduino Due Board. Among its features, the most important characteristics for the simulator design are its 54 digital I/O pins, 12 analogical inputs and the reset and erase buttons [2]. Moreover, the Arduino Due board has an operating voltage of 3.3V, a Programming Port and a Native USB Port.

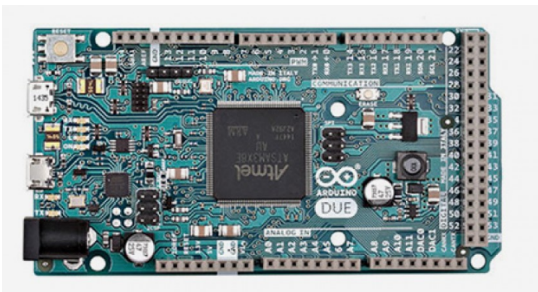

Figure 3.11: Arduino Due board [2].

The micro controller of the Arduino board is in charge of sending and receiving the information about the simulation case. The information is provided by the web interface in the Raspberry Pi. Both Arduino Due and Raspberry Pi boards are connected by the serial port.

The Raspberry Pi and the Arduino board are the elements in which the data communication is generated. They are connected by the serial port and send the data for the bleeding action. The complete electronic schematic is shown in Figure 3.12.

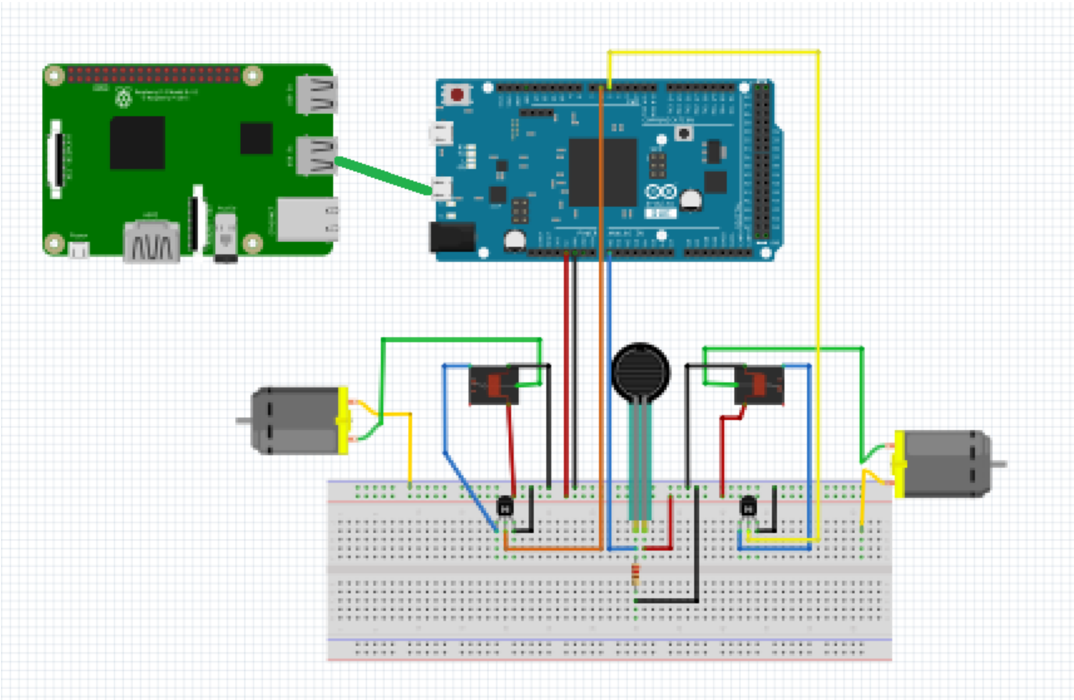

Figure 3.12: Electronic schematic.

The hardware design is very important for the clinical application of the bleeding trauma simulator. The electronic control design executes the data communication between the web interface and the simulator, allowing a real time interaction. The electronic design is fundamental for the correct functioning of the bleeding performance, providing different possible scenarios. The mechanical design facilitates the approval of the medical teams, helping the simulator to have a more realistic physical appearance.

Chapter 4

Software Design

4.1 Software requirements

The software design provides the specific characteristics of the simulator, including its functionality, adaptability and connectivity. The software has been developed in line with the following requirements:

- Software has been designed in order to provide a simulator capable of reproducing different bleeding trauma scenarios, differentiating between arterial and venous bleeding, and central and peripheral blood vessels.
- The simulator has to be controlled from an intuitive and user friendly interface, providing a real time connection.
- The bleeding trauma simulator has to be able to reproduce different patient scenarios. Moreover, the simulator has to be able to be integrated in any type of simulator (high or low fidelity) providing a high usability.

4.2 Project software design

In this Master Thesis, as stated before, the objective is not only to develop a bleeding trauma simulator but also to control and configure it following the simulation needs as explained in Chapter 2. In order to fulfill these requirements, a web interface has been developed for the bleeding control and configuration, as well as the bleeding trauma simulator.

The communication port for receiving and sending data is made by the Serial Port, which connects the Web Interface and the Arduino. As stated in Chapter 3, the web interface is hosted and launched from the server, which is the Raspberry Pi. The simulator is composed of the different sensors and actuators controlled by the Arduino. This connection provides a real time interaction; therefore, the simulations can be controlled at any time during the bleeding scenario.

As shown in Figure 4.1, the software design has been organized in three main parts: the web development, the communication and the simulator software. All these parts are connected to each other providing a control loop of the simulation process.

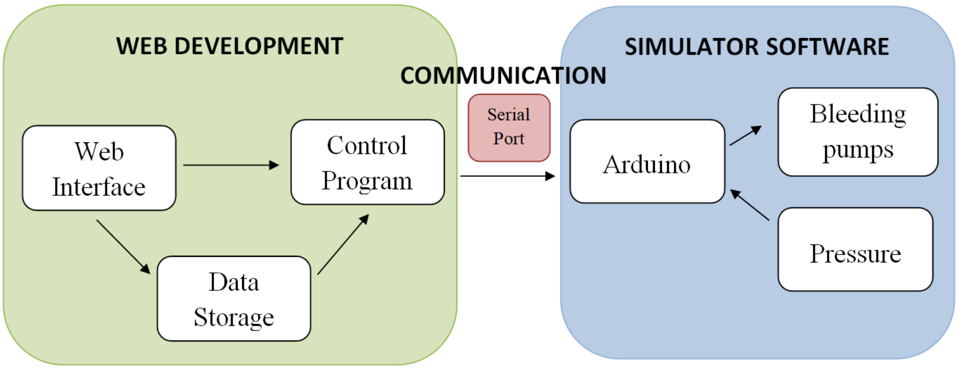

Figure 4.1: Software schematics.

The interaction between the web and the bleeding trauma simulator occurs due to the communication established by the serial port, which sends the bleeding order from the interface to the simulator. The simulator, takes the information of the pressure sensor located near the bleeding injury. This sensor provides information about the bleeding control, which is an important aspect in the bleeding trauma protocol. Details about the software development are explained in the following.

4.2.1 Web development

The development of a web interface to control the simulator provides access to the configuration of different bleeding scenarios. Clinical simulators offer a learning method complementary to theory; therefore, having a bleeding module with this features would increase the variety of simulation cases. This variety allows clinicians to practice more clinical scenarios. Moreover, the need of a user friendly interface provides flexibility to the user, giving the possibility to configure it as needed in order to practise all types of scenarios. With the web interface, technicians can control the hemorrhage scenario while the clinician is practising.

PHP and HTML programming languages have been used to develop the web interface. On one hand, PHP code is executed on the web server. It is in charge of obtaining the parameters of the selected configuration. Moreover, it stores the data of the next execution in the corresponding files so that they can be sent to the simulator. On the other hand, HTML code is executed on the client side. It defines the structure and the design of the web as well as it provides the information to PHP via POST instruction.

The web interface has been developed following the requirements for the target user of the simulator and it has the following characteristics:

- A user friendly interface has to be developed in order to facilitate the management and control of the bleeding trauma simulator. It has to be intuitive and easy to use.
- A data collection that the trainer would like to include in any specific simulation, store them to later on analyze the training outcome and progress.
- Flexibility in order to provide the option to shape different scenarios manually, differentiating between arterial and venous bleeding.

In order to get all these characteristics, the web interface has been designed as shown in Figure 4.2. The web interface is divided into two different sections: one section corresponds to the manual configuration scenario (left), and the other one contains the scenarios programmed according to the Chapter 2.

On top of the web interface, the name of the scenario or the name of the trainer, can be put in order to reference the simulation.

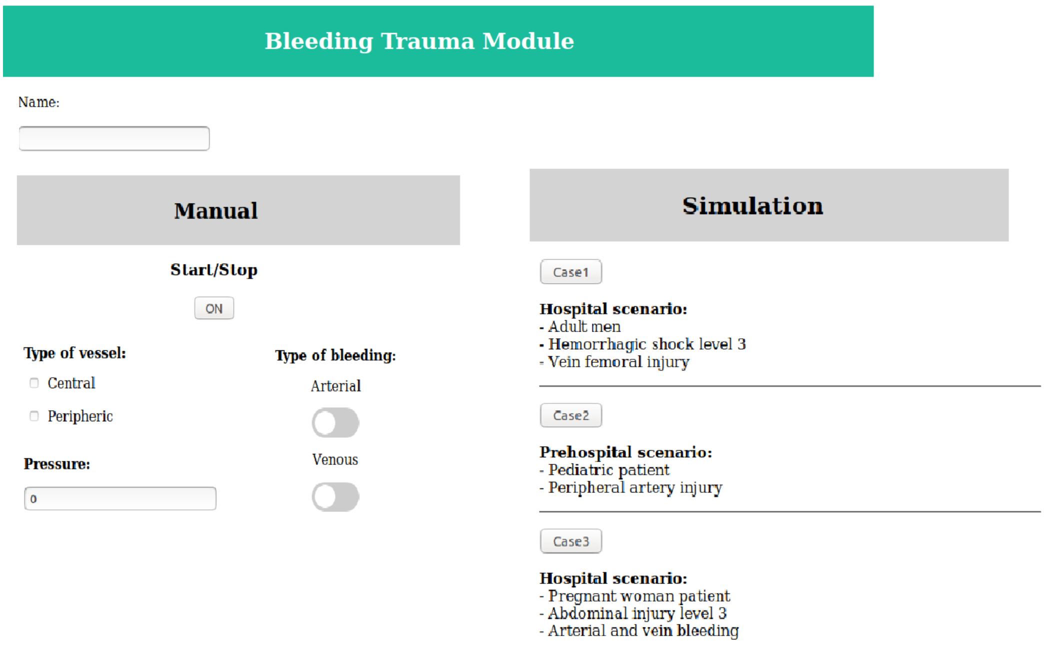

Figure 4.2: Web Interface.

The manual configuration section allows the trainer to set-up the scenario with the needed parameters. The combination of the different simulation parameters provides a wide range of simulation possibilities. This section is composed of:

- A start/stop button, which submits the bleeding scenario. When the ON button is clicked, it submits the status of the hemorrhage with the type of bleeding selected: arterial or venous. The simulation stops when the ON button is clicked again.

- Two switch buttons to configure the type of bleeding (arterial and/or venous). It can be one or both buttons selected, depending on the bleeding needed.

- Two check buttons to select the location of the vessel: central or peripheral. These buttons adjust the pressure needed to make when trying to control the hemorrhage. Different values of pressure are configured for each vessel location.

- The pressure section shows the pressure exerted when controlling the hemorrhage. This value comes from the pressure sensor inside the skin of the bleeding trauma simulator.

The case planned section of the web interface is composed of three pre-defined scenarios. This section is developed in order to help and facilitate the trainer work. Instead of programming the scenario every time, it can be executed by clicking the button of the selected case. The three cases pre-defined in the interface correspond to different scenarios where the hemorrhage protocol changes depending on the patient conditions and characteristics.

4.2.2 Communication

Once the simulation scenario is set, the PHP file stores the data in several files and a python script reads them in order to send the hemorrhage status to the serial port (see Figure 4.3). One file is used to collect the execution order and the other one to collect the simulation parameters.

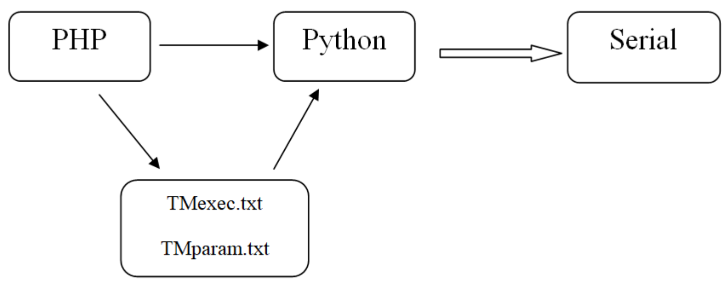

Figure 4.3: Communication flow diagram.

In the execution file (TMexec.txt), a 1 or 0 is collected depending on the Start/Stop button condition. The number 1 stands for Start and the 0 represents the Stop communication status.

In the configuration file (TMparam.txt), the bleeding data is collected. It stores the name of the trainee, the arterial and vein bleeding status and the central or peripheral vessel location.

The python script is always executed as the web is running. It is in charge of reading and collecting all the simulation information and establishing the communication through the serial port. Detailed information about these two functions are explained below:

- Read data from files: The data stored in the files mentioned before is read and treated. The python script separates each data obtained from the files. It takes the execution order (Start/Stop) and the type of simulation to execute (arterial or venous and central or peripheral).
- Send data to Arduino: Python obtains the information about the bleeding simulation parameters and sends it to the Arduino. The bleeding status, as shown in Table 4.1 is sent.

Status	Execution	Arterial	Venous
Stop (0)	1	0	0
Arterial (1)	1	1	0
Venous (2)	1	0	1
Arterial and venous (3)	1	1	1
Off communication (4)	0	-	-

Table 4.1: Communication status.

The communication between the web interface and Arduino is set when the bleeding status is sent by the serial port. Arduino receives it and activates the corresponding bleeding simulation.

4.2.3 Simulator software

The Arduino software is in charge of the bleeding trauma activation when it gets the bleeding status from the web interface. Arduino waits until the serial port sends the status through the Serial.available() instruction. When it obtains data, it reads the Serial Port and activates the corresponding bleeding action.

Arduino provides an output signal, which corresponds to the pumping activation, and receives an input signal coming from the pressure sensor. The pressure sensor provides useful information on how the bleeding is being treated and whether it is being controlled. The output signal is set in two digital pins, for the arterial and venous pumping relay activation and the input signal is set in an analogical pin in order to read the pressure measurement.

As the arterial and venous bleeding are physiologically different, its activation are separately configured. The arterial bleeding is activated and deactivated every 200 milliseconds, while the venous bleeding is continuously activated.

On the other hand, a timer has been set in order to obtain the pressure sensor measurements. The timer operates at the same time as the pumping activation with a 200 milliseconds frequency. Moreover, the pressure data is stored in order to see the progression of the hemorrhage control during the simulation.

The pumping system, activated via the web interface, can be deactivated by pressuring the injury or via the web interface. The objective of this feature is to provide a more realistic feedback to the trainee. In case the trainee follows the protocol and controls the hemorrhage pressuring the injury, the bleeding gets stopped. The pumping is activated by the level up of the digital pins in the Arduino when the simulation need to activate the bleeding. Each bleeding activation is connected to one digital pin.

Chapter 5

Results and Clinical Validation

In this Chapter, the final results of this Master's Thesis are presented. First of all, the results obtained from the bleeding trauma simulator and the web interface will be presented. Then, the clinical validation of the complete solution from the hospital's HULP medical team will be shown .

5.1 Results

In this Section, the results obtained in this Master's Thesis are presented. The results of the development of the web interface and the simulator will be shown in the following:

- **Bleeding trauma simulator**

  The simulator developed consists on a silicone skin (simulating the human skin) which holds, as shown in Figure 5.1, two flexible ducts: one arterial and another one for venous bleeding and a pressure sensor.

Figure 5.1: Bleeding trauma simulator.

The final design of the simulator consists on a small pack where the tank and the electronics are placed separately in order to hide all components which does not belong to clinical equipment, and to promote a realistic clinical scenario. Moreover, the retractile effect of skin provides a more realism scenario. It is an adaptable skin band which can be integrated in any body surface.

As soon as the trainer executes the start button in the web, the simulator will receive the hemorrhage status and will start the bleeding simulation. Depending on the status received, the simulator will execute Arduino simulating the specific status introduced. As shown in Table 5.1, three possible hemorrhage status can be executed. The bleeding will be constantly executed until the trainee controls the hemorrhage by following the bleeding trauma protocol or when the trainer stops the simulation.

Status	**Description**
0	Off status
1	Arterial bleeding
2	Venous bleeding
3	Arterial and venous bleeding

Table 5.1: Bleeding status.

- **Scenario results**

  As stated above, the simulator is able to reproduce several bleeding trauma scenarios by its configuration in the web and can be adaptable to different bleeding trauma simulation cases.

  In order to add more value to the clinical simulation with this bleeding trauma module, a function to detect hemorrhage control performed by the person practicing the simulation case has been incorporated. This feature provides feedback about some of the protocol steps to follow in order to stop the hemorrhage.

  During the simulation, the hemorrhage is characterized by the type of bleeding (see in Table 5.1) and the location of the vessel (central or peripheral). The results of the simulation are presented in two different tests: one of the arterial and venous bleeding, and the other one which shows the bleeding action as a function of the pressure exerted in the injury.

  - **Type of bleeding**

    The simulator is able to execute two types of bleeding due to the pumping system implemented on it. There are three possible bleeding scenarios depending on the configuration selected: arterial, venous or both. The results of these three types of bleeding scenarios are shown in Figures 5.2, 5.3, 5.4, where the Y axis represents the pin value of the Arduino board as a function of the time represented in the X axis.

∗ **Arterial bleeding**
The arterial pump is activated and deactivated every 200ms. The venous pump is set at LOW level.

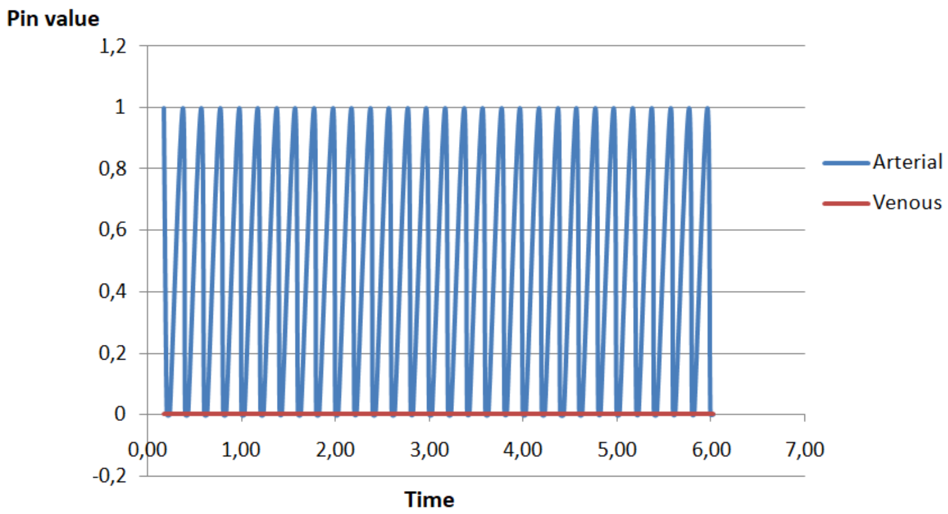

Figure 5.2: Arterial performance.

∗ **Venous bleeding**
The arterial pump is deactivated and the venous pump is set to HIGH level.

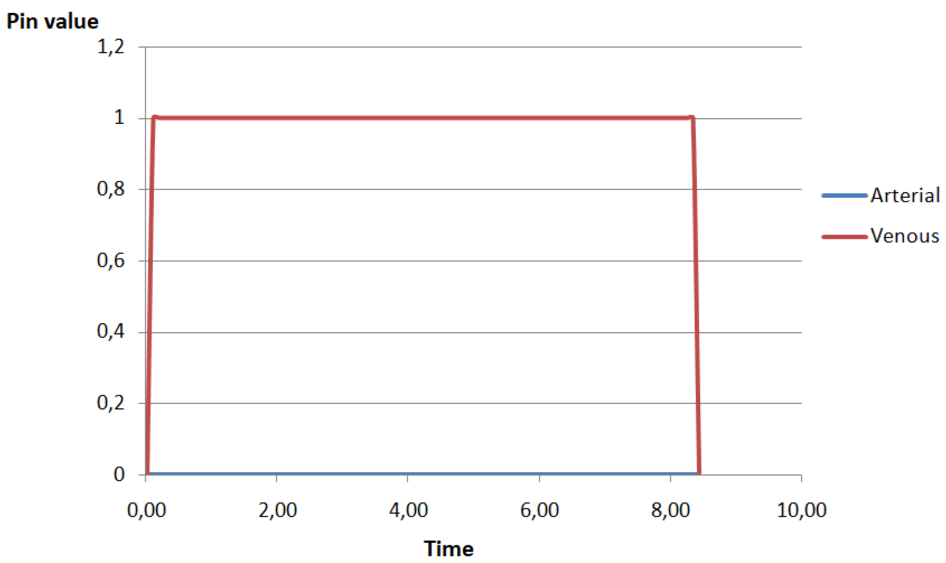

Figure 5.3: Venous performance.

* **Arterial and venous bleeding**
  Arterial is activated in intervals of 200ms and the venous pump is activated.

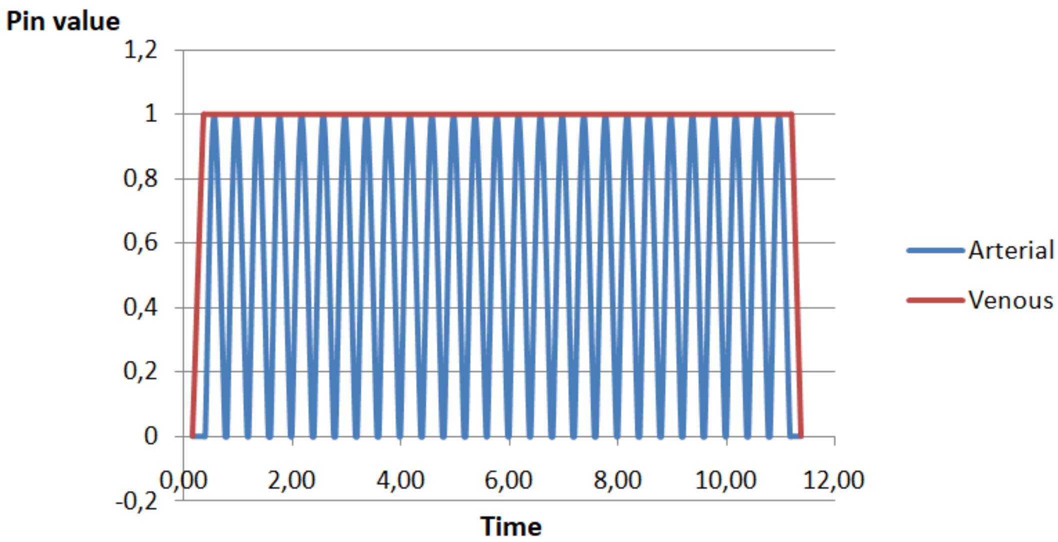

Figure 5.4: Arterial and venous performance.

As shown in Figures 5.2 and 5.4, the arterial bleeding is performed as a pulsating actuation in intervals of 200ms. This value similarly corresponds to the arterial pulse. The venous bleeding is represented as a constant value.

In these three graphs, the activation of the relays stays at 1 because of the high level activation of the digital pins. When the bleeding is deactivated, it takes a 0 as the low level.

– **Bleeding performance**
  The location of the vessel will be defined with the pressure threshold needed to be done to control the hemorrhage. In case of a central vessel, the threshold to control the bleeding will be higher than the pressure needed to control an hemorrhage on a peripheral one due to its importance in the cardiovascular system.

  The pressure to control an hemorrhage is not always the same and there is not a stipulated pressure value to control it. For this reason, some tests have been performed with medical doctors to establish an approximate value for these.

  The Arduino board, when reading the pressure exerted in the sensor, shows the analogical lectures, from 0 to 1023, which represents the resistance voltage, from 0 to 5 Volts. In the tests with clinicians, 600 and 1023 have been selected as the two thresholds for peripheral and central blood vessels which corresponds to 2,93V and 5V respectively.

Following the previous considerations, the results of some simulated scenarios are presented below:

* **Peripheral arterial bleeding (threshold=600)**

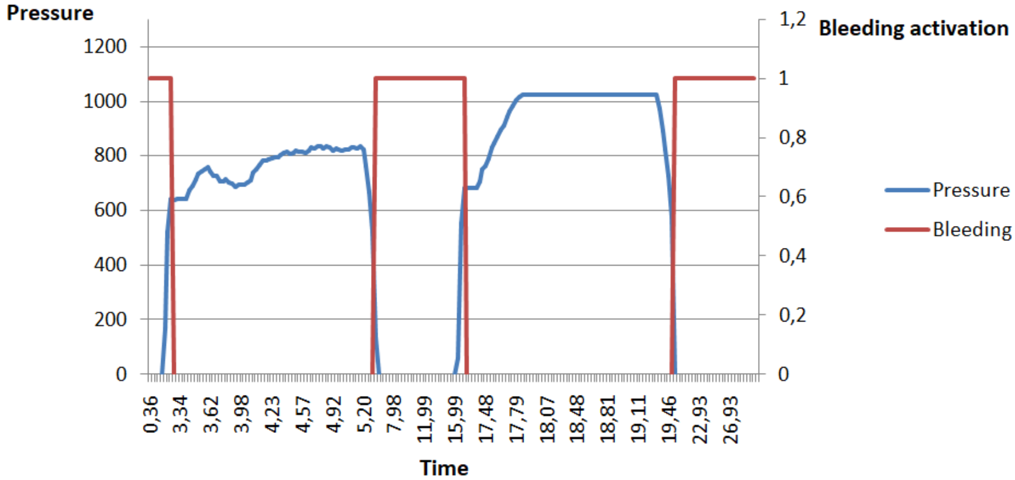

Figure 5.5: Peripheral bleeding action.

* **Central vein bleeding (threshold=1023)**

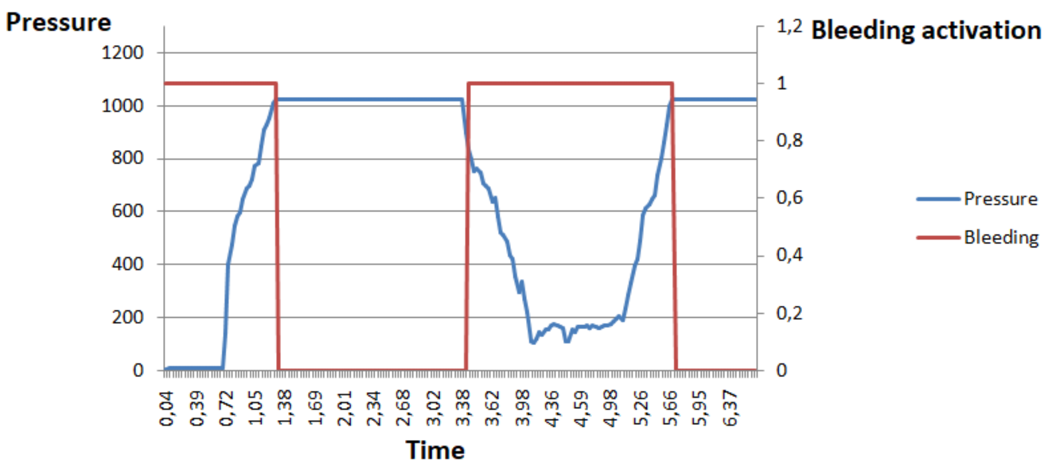

Figure 5.6: Central bleeding action.

In these results the differences between venous and arterial bleeding are not shown since the objective of the study is the action of bleeding as a function of the pressure exerted on the wound.

In the three cases, the bleeding action (represented in red) varies as the pressure sensor gets to the threshold value (represented in blue). In case of a central bleeding, both arterial or venous, the bleeding performance will stop when the pressure gets the value of 1023. In case of a peripheral bleeding, the hemorrhage stops when the pressure sensor gets values of 1023 and higher.

The bleeding progress as a function of the pressure exerted provides an important information about the evolving of the trainees simulation. Moreover, these results can be used for the pre-defined scenarios of Chapter 2 and make them change during time.

5.2 Clinical Validation

The clinical validation of the simulator has been done with clinicians from different hospitals. Medical professionals from different hospital units have evaluated the simulator and the web interface in order to get a complete feedback.

The clinical validation was done taking into account the following aspects:

- **Simulator validation:** the simulator has been tested with different types of bleeding trauma scenarios. All possible scenarios have been simulated with the complete assembly, including the skin placed on an simulator arm and a red dye for the blood.
- **Web Interface validation:** the web for the simulator control has also been tested by the clinicians who have tried to control the simulator by themselves applying different scenarios and testing all the options that the interface provides.
- **Suggestions and comments:** After showing the complete project, clinicians were asked to provide their opinions and suggestions in order to get feedback on what could be improved.

In order to get their feedback of these three aspects, a questionnaire has been given with different questions about the three parts previously mentioned. The main style of the questions are not yes and no answers, but rather, through an evaluation of points between 1 to 5, being 1 the lowest and 5 the highest, the clinician is able to evaluate this solution more in detail.

The questions included in the questionnaire are the following:

1. Do you find it useful for learning hemorrhage protocols?
2. How would you rate your experience with the simulator?
3. Do you think it helps critical thinking and decision making?
4. Do you think the web is intuitive?
5. Do you think the structure of the web is comfortable?
6. Are the bleeding scenarios realistic?
7. Would you consider it interesting to incorporate a function to detect the pressure exerted on the wound in order to control bleeding?
8. Do you consider necessary to include the simulation time on the web for the evaluation of hemorrhage shock?
9. Is its size adequate for the simulation of bleeding scenarios?
10. Do you think the simulator motivates learning?
11. Has the overall experience been satisfactory?

Moreover, questions about their age, profession, work unit and work centre were asked in order to evaluate the application of the clinical simulator. Their age provides a feedback about using new technologies and their motivation for learning with new learning techniques. The work unit and their profession provides details about possible suggestions in order to prepare the bleeding trauma scenarios for every medical team, and the aspects in which they are more interested to simulate in the clinical scenarios.

Medical teams have evaluated the simulator as very useful for learning as well as for critical thinking and decision making. On the other hand, they confirm that the web is intuitive and has a good structure which helps the control of bleeding scenarios. Clinicians find the bleeding scenarios very realistic and the skin helps to get a real bleeding trauma scenario.

The answers of the questionnaire helped to find which aspects of the simulator are most important to be improved. One of these solutions proposed is the incorporation of a timer in the web interface will help in order to make an evaluation of the medical condition of the patient during the simulation. The results of the questionnaire fulfilled by the clinicians are found in Annex C.

Chapter 6

Conclusions and future developments

6.1 Conclusions

Fulfilling the objectives of this Master's Thesis, a bleeding trauma simulator for clinical simulation has been developed as well as a web interface to control the simulation scenario. Due to the project results and the clinical validation, this simulator fulfills all the criteria that would be needed in the Hospital Universitario La Paz in order to incorporate a new learning method in clinical simulation.

The simulator developed is adaptable to different scenarios, being able to set up the type of bleeding actuation and the location of the affected blood vessel. In addition, the simulator does not only execute a bleeding trauma injury but also provides feedback when the injury is being controlled as the wound is pressed. The fact that the simulator provides a feedback means that this bleeding trauma simulator could be considered as a high fidelity clinical simulator.

Taking into account the existing simulators and those which are normally used in simulation scenarios, this bleeding simulator offers automatic control of the bleeding trauma scenario. These features allow a better and more comfortable control over it and does not need any auxiliary person creating the bleeding manually. Its structure also allows it to be used in all types of simulators: actors, high fidelity and low fidelity simulators, which provides a wide range of use for any type of clinical simulation in which the cardiovascular system is affected.

The bleeding trauma simulator and the web interface have been created from scratch. The study and learning process of PHP, HTML and python languages have been really helpful in order to think about more features to be implemented in the simulator. Moreover, the study of bleeding trauma related to this Thesis has contributed to understand some aspects of the protocols to be performed in case of a hemorrhagic emergency, and to gain knowledge about some physiological functions of the human body.

6.2 Future developments

Once the results and conclusions of this Master's Thesis are presented and taking into account the clinical validation at the hospital, some future lines are presented:

- The improvement of the blood vessels system by changing them to thinner and more flexible tubes. The purpose will be to detect the arterial bleeding not only by the visualization of its pulse but also by taking the pulse touching the skin like the normal procedure.
- The incorporation of more characteristics and functions such as the variation of the pulse frequency over the time or a ECG monitor in the web to see its variation.
- The creation of a database to store the data of each simulation scenario. This option will allow the hospital to analyze the progression of each trainee or to search previous simulations and get the simulation data.
- The incorporation of a configuration section for planned simulation. This would help trainers to configure other programmed scenarios.
- The adding of a feature that controls the bleeding flow. Mechanical valves can be implemented in order to perform different bleeding flows.
- The creation of a vascular map of some body parts, such as the extremities, which can be used for specific clinicians such as the perfusion unit or nursing.
- A monitoring and training process of the bleeding and pressure performance will promote the study of the incorporation or adjustment of different protocols to practise in clinical scenarios.

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Appendix A

Impact

A.1 Introduction

In Spain, bleeding trauma injury presents one of the most leading causes of death after circulatory diseases, tumors, respiratory, nervous system, and mental disorders. Approximately 80% of adolescent deaths and 60% of adolescent deaths are due to trauma injury.

This Master's Thesis pretends to be an effective learning method to practice bleeding trauma protocols. The objective of this project is to avoid hesitations and to help the critical thinking when an urgent patient with bleeding trauma injury needs to be attended.

A.2 Description of relevant impacts related to the project

- Social impact: This project will have a direct impact on medical teams, who work attending bleeding trauma patients. Medical teams can benefit from this automatic learning simulator which helps them to practice control hemorrhage protocols. Moreover, a big part of the population can benefit indirectly from this simulator as they might have this type of injury and need urgent care. The use of technologies that allow a wireless connection and a control over an electronic circuit add value to the simulation and promotes the improvement of simulators in order to obtain a better learning process.

- Economical impact: This project will have an economical impact on the use of the simulator thanks to its reduced cost and the different variants offered by the configuration of scenarios, without the need of any other simulator. In addition, this simulator and its control web is prepared for bleeding trauma but it can also be used for any fluid control.

- Ethical impact: The practice with the bleeding trauma simulator can benefit the number of tests to patients, avoiding suffering and complications during a bleeding trauma. The practical sessions with the simulator will improve their technique following the hemorrhage control protocol and a fast decision making in case of complications during the patient care.

- Legal impact: The research and development activities carried out during this Master's Thesis are framed within the "Law on Biomedical Research" 14/2007 (BOE 159, July 4, 2007). The collaboration with the Hospital Universitario La Paz in the development of this thesis and its possible patent are framed in the "Law on Science, Technology and Innovation" 14/2011 (BOE 131, June 2, 2011).

- Environmental impact: There is no environmental impact in the development of this Master Thesis.

A.3 Conclusion

The development and implementation of a bleeding trauma simulator for clinical simulation will cause a direct impact to the medical teams which are the target of this project. The use of actual technologies in simulators will increase the adaptability of learning methods with realistic scenarios in order to improve not only technical skills but also personal ones.

The possibility of using the simulator at any time for different medical teams promotes the future treatment of patients. This solution will help to improve diagnosis and decision making in cases of bleeding trauma injury where the life of the patient is at risk.

Appendix B

Economical Budget

This Master's Thesis has been developed during 4 months. The economical budget is calculated taking into account human resources, technical equipment and the material resources.

- **Human Resources costs**

  The salary of all people involved during the development of the project should be considered. The medical doctor, simulation technician and the engineering student costs as shown in Table B.1.

	Cost per hour(€)	Working hours	Total costs (€)
Medical doctor	25	30	750
Simulation technician	15	100	1.500
Engineering student	10	500	5.000
Total			**10.850€**

Table B.1: Human Resources budget.

- **Material Resources costs**

  The costs of the technical equipment and material resources used for the project development are listed in Table B.2. The total costs are calculated taking into account the costs per unit, the amortization in years and the time used in months.

	Units	Cost(€)	Time used (months)	Amortization (years)	Total costs (€)
Raspberry Pi	1	36,40	4	5	2,43
Arduino Due	1	28,50	4	5	1,90
Relay	2	0,92	4	5	0,12
Pressure sensor	1	8,00	4	5	0,53
Liquid pumps	2	3,00	4	5	0,40
Other electronics	1	6,00	4	5	0,40
Other materials	1	25,00	4	5	1,66
Personal computer	1	1.500	4	5	100,00
Total					**107,44(€)**

Table B.2: Material Resources budget.

- **Total costs**

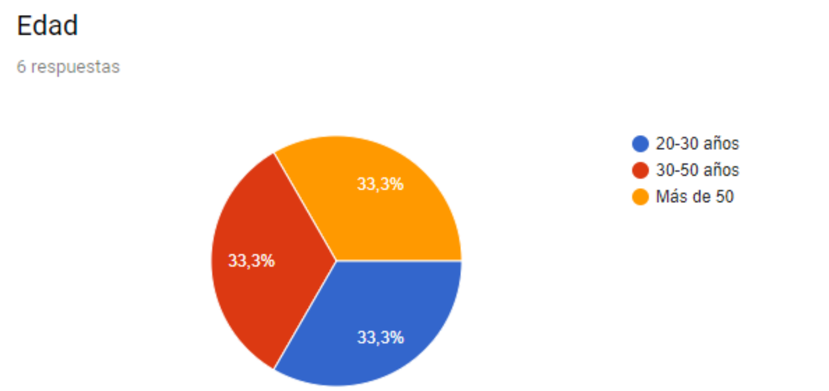
  The total costs are presented in the Table B.3. It is calculated taking into account the general costs (15% of direct costs) and the industrial benefit (6% of the direct and indirect costs). The total costs of the Master's Thesis is 16.292,11€.

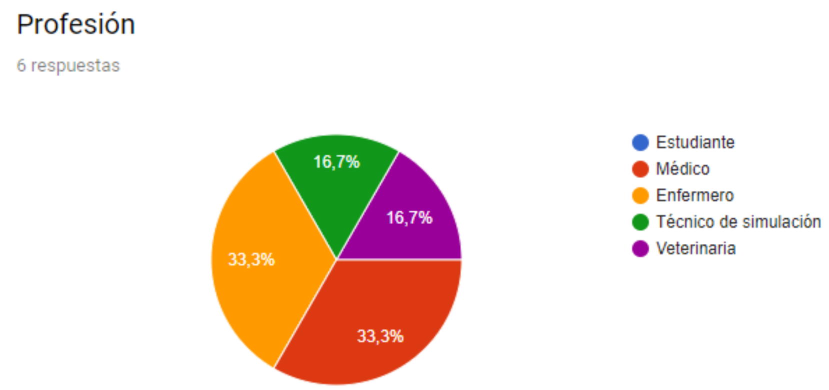
	Cost (€)
Human Resources	10.850
Material Resources	107,44
General costs (15%)	1.643,62
Industrial benefit (6%)	756,06
IVA (21%)	2.810,79
Total	**16.292,11€**

Table B.3: Budget.

Appendix C

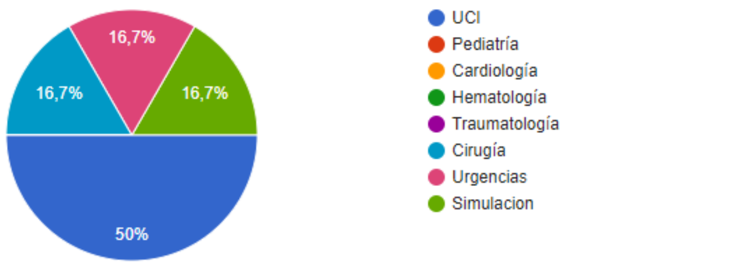
Clinical Validation Questionnaire





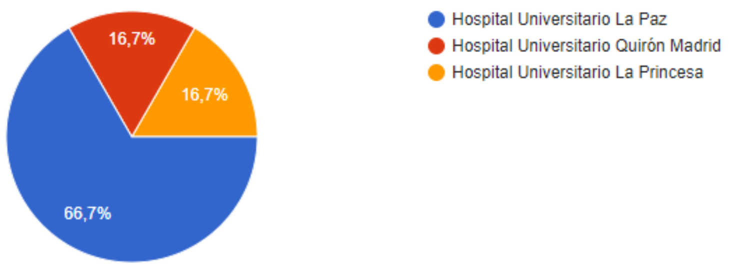
Especialidad

6 respuestas



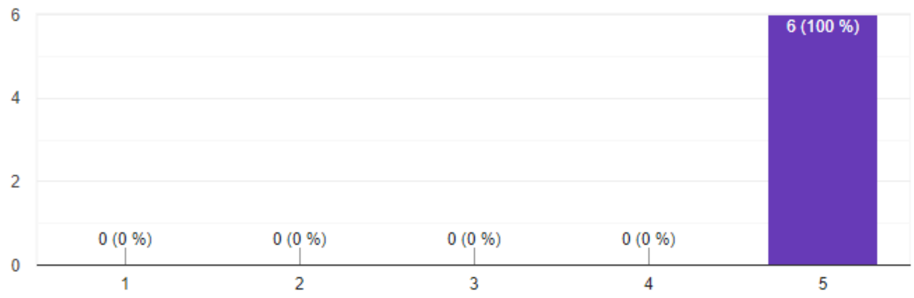
Centro de trabajo

6 respuestas



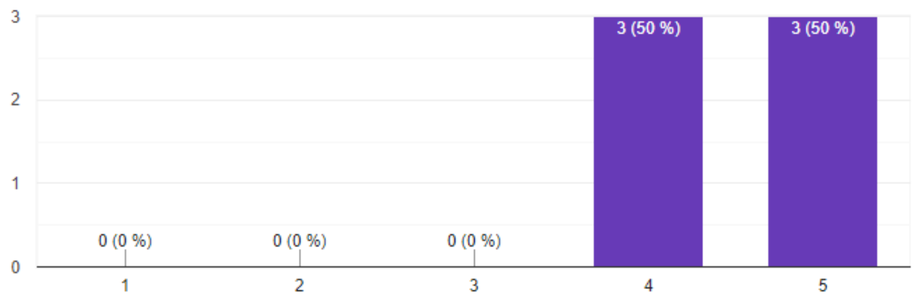
1. ¿Consideras que es útil para el aprendizaje?

6 respuestas



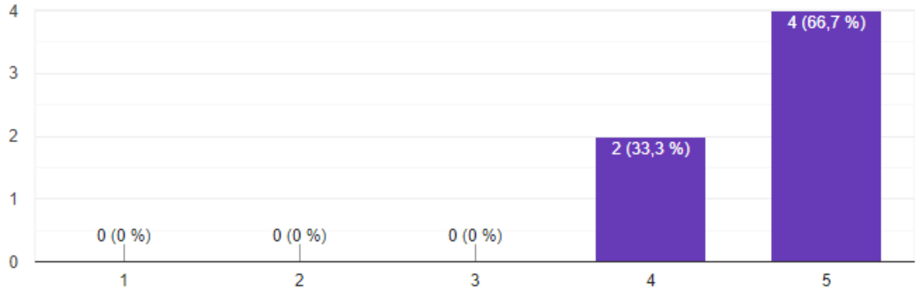
2. ¿Cómo calificarías tu experiencia con el simulador?

6 respuestas



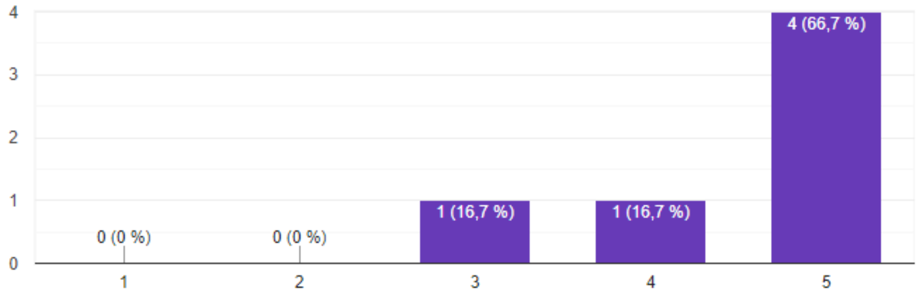
3. ¿Crees que ayuda al razonamiento crítico y a la toma de decisiones??

6 respuestas



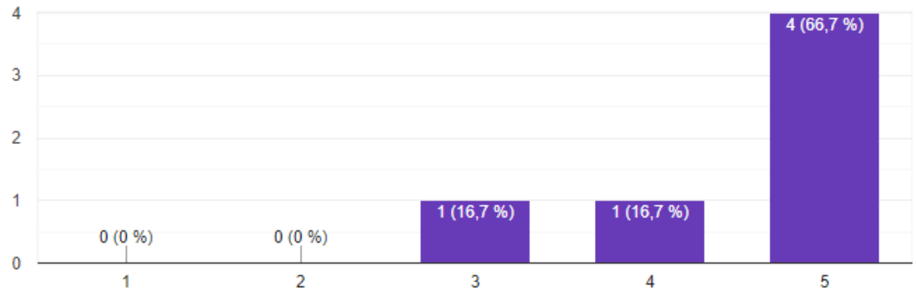
4. ¿Crees que la web es intuitiva?

6 respuestas



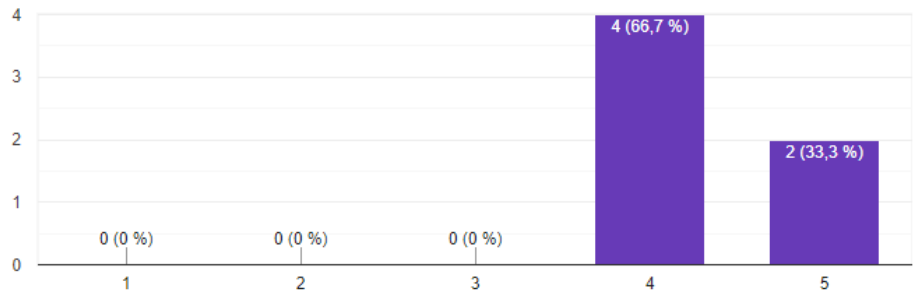
5. ¿Te parece cómoda la estructura de la web?

6 respuestas



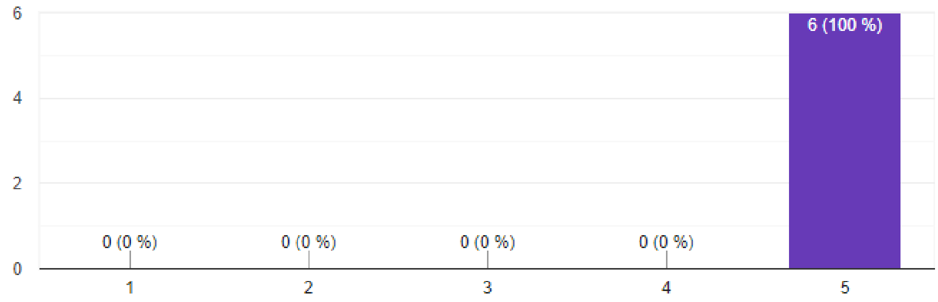
6. ¿Los escenarios de sangrado son realistas?

6 respuestas



7. ¿Considerarías interesante incorporar una funcionalidad para detectar la presión ejercida en la herida para el control de la hemorragia?

6 respuestas



8. ¿Consideras necesario el incluir el tiempo en la web para la evaluación del estado de shock hipovolémico?

6 respuestas

Si

Sería buena idea

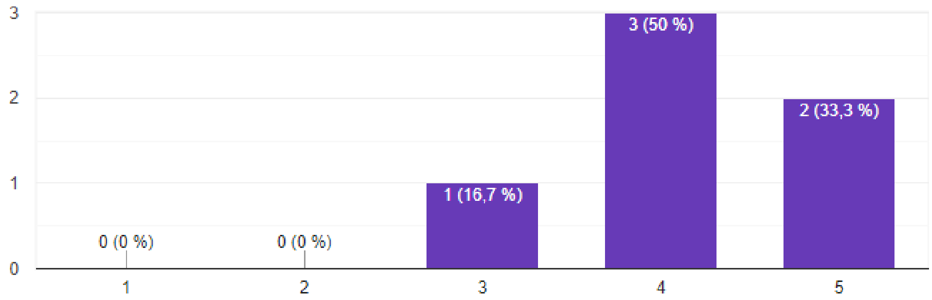
Si ayuda al conocimiento del tiempo de reacción ante una situación de sangrado masivo

No tanto, realmente este es un aspecto dicitòmico, o se controla elnsangrado mecánicamente o no

Si, ya que es una emergencia tiempo dependiente

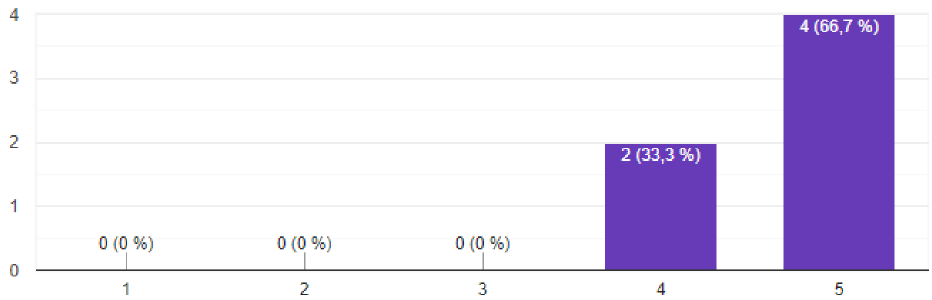
9. ¿Su tamaño es adecuado para la simulación de escenarios de sangrado?

6 respuestas



10. ¿Crees que el simulador motiva el aprendizaje?

6 respuestas



11. ¿La experiencia general ha sido satisfactoria?

6 respuestas