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## Mechatronic system for performing blood pre-transfusion tests

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#### ABSTRACT

The blood types determination is essential to perform safe blood transfusions. In emergency situations is administrated the "universal donor" blood type. However, sometimes, this blood type can cause incompatibilities in the transfusion receptor. A mechatronic prototype was developed to solve this problem. The prototype was built to meet specific goals, incorporating all the necessary components. The obtained solution is close to the final system that will be produced later, at industrial scale, as a medical device. The prototype is a portable and low cost device, and can be used in remote locations. A computer application, previously developed is used to operate with the developed mechatronic prototype, and obtain automatically test results. It allows image acquisition, processing and analysis, based on Computer Vision algorithms, Machine Learning algorithms and deterministic algorithms. The Machine Learning algorithms enable the classification of occurrence, or alack of agglutination in the mixture (blood/reagents), and a more reliable and a safer methodology as test data are stored in a database. The work developed allows the administration of a compatible blood type in emergency situations, avoiding the discontinuity of the "universal donor" blood type stocks, and reducing the occurrence of human errors in the transfusion practice.

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#### 1. Introduction

The determination of the blood type is essential before carrying out a blood transfusion, ensuring the administration of a compatible blood type. Pre-transfusion tests are performed to determine blood type and ensure the compatibility required to perform the transfusion. To this end are available different test procedures, in particular the plate test, the tube test, the gel centrifugation test, and the micro plates test [1,2]. Considering these test procedures, the plate test and the tube test are those which are best suited for emergency situations since they require only between 5-10 min to perform the test procedure and obtain the results [3-11]. However, as these tests are manually performed, there is the possibility of human mistake or oversight, associated either to the test procedure, or to the reading and interpretation of results. Accordingly, several systems have been developed with the aim of automating the steps involved in the realization of pre-transfusion tests, including reading and interpreting results. However, despite the wide range of currently available commercial systems, the achievement

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http://dx.doi.org/10.1016/j.sna.2016.05.022 0924-4247/© 2016 Elsevier B.V. All rights reserved. of pre-transfusion testing in emergency situations remains a challenge. In emergency situations, time is short and a fast response is necessary in order to quickly restore the volume of blood lost. In these situations, to conduct ABO and Rh pre-transfusion tests with the available systems is necessary to transport the blood sample taken to the laboratory where the systems are stored. This happens because of the fact that the systems are large, heavy, and are not easily transported and so they can only be used in a laboratory. In this context, the total time before being able to make the transfusion increases because of the longer times needed to obtain results with the aforementioned systems and the time required to travel to the laboratory and the travel needed in order to administer compatible blood. In Table 1 are presented the orders of magnitude of the times involved in the use of some of the commercial systems. They show that none of these systems can give results in less than 10 min. Thus, for ABO and Rh test, the Echo system is the one which allows obtaining results in a shorter time, followed by the Galileo [12], Tango Optimo [13], AutoVue Innova [14] Wadiana [15], Qwalys 3 [16], and ProVue [17] systems.

The need of travel to the laboratory together with the times already required by current systems (about 15–20 min) [4,10] Table 1, led to respond timely to the needs in emergency situations; it was agreed that in these situations it is administered the blood type O negative (zero or negative), considered the universal donor,

#### Table 1

Duration of ABO and Rh Tests on a Few Commercial Systems [10,1	13,15,18]	•
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	Systems							
	Galileo	ProVue	Echo	AutoVue Innova	Tango Optimo	Qwalys 3	Wadiana	
Time to perform ABO and Rh tests (minutes)	15	35-40	11	20	17	30	30	

which provides less risk of incompatibilities [19–23]. However, despite using this type of blood with a low risk of incompatibilities, sometimes it can cause some transfusion reactions which may worsen the clinical condition of the recipient of the transfusion and therefore this should be prevented. Thus, this practice of blood transfusion based on universal donor is reserved for emergency transfusions, where there is no safer alternative [19–21]. Taking this into consideration, it is concluded that pre-transfusion tests should be performed before any transfusion in order to prevent incompatibilities.

It can be noted that the ABO and Rh incompatible transfusions, caused by human error, are one of the most serious problems associated with transfusions [24,25]. Reports of a conducted study in 2004 indicate that the main causes of error in transfusion are the flaws in the identification of blood components, in the recipient's identification, and in the determination of ABO blood type, and some of these errors caused primarily by nurses and doctors to "head" of the individual receiving the transfusion [22–27]. These errors led to the fact that in the recent years, it was guite frequent for an individual to receive a unit of blood/component of the wrong blood type than contracting an infection by receiving a transfusion. It appears that the human error associated with blood transfusion is frequent and must be eliminated to make safer blood transfusions [26]. Latest reports from the FDA (Food and Drug Administration) presented data on the number of deaths reported to the FDA from 2008 to 2012. The data show that the risks associated with blood transfusion have been declining, verifying that the number of deaths associated with blood transfusion is smaller against the total number of performed transfusions [27,28]. In 2008 were transfused nearly 24 million of blood components [27,28] and were identified 46 fatalities associated with transfusions. In the following reports for 2009, 2010, 2011 and 2012 were identified 44, 40, 30, and 38 fatalities [28].

Furthermore, the lack of blood has increased and blood group O negative has been more requested, especially in emergency situations [29]. This generates a need for logistic efficiency to keep balance the blood supplies in certain countries or regions. In addition, processing, transportation and storage of blood is complex resulting in regions with a greater risk of lack of blood [30,31].

#### 2. Theory

Blood is a liquid tissue that circulates in the body through veins, capillaries and arteries and it is composed of plasma and cells that are suspended in plasma, namely: red blood cells, white blood cells, platelets and coagulation factors [19,32]. The red blood cells have on their surface antigens that can be of a varied bio-chemical nature. The antigens of each individual are ignored by the immunity system, but in the case of antigens present in the donated red blood cells, which are different from the individual's antigens, the immunity system attacks the red blood cells causing a reaction. In turn, the plasma contains other substances known as antibodies. The antibodies are specific and can only be combined with the corresponding antigen. If the antibodies that are in the plasma bind to antigens of red blood cells, often called agglutination [19].

The ABO system is composed of four different blood types, A, B, AB, and O type. These types of blood are generally characterized by

the presence or absence of antigens on the surface of red blood cells, but they may also be characterized by the presence or absence of antibodies in plasma. In this system there are two types of antigens A and B and two types of antibodies, Anti-A and Anti-B. Thus, type A individuals have the A antigens on their red blood cells, type B individuals have B antigens on their red blood cells, type AB individuals possess both types of A and B antigens on their red blood cells and, finally, there are individuals that do not possess antigens A or B into their red blood cells. In each individual antibody compatible with the antigens of the red blood cells can only exist in their plasma. For example, one individual of type A has A antigens on their own red blood cells and cannot have in their plasma anti-A antibodies because an agglutination reaction will occur in their red blood cells. Similarly, individuals with B antigens will have an agglutination reaction in case anti-B antibodies are in their plasma [1,19,33].

In addition to the ABO system, there is one other system clinically relevant in the context of blood transfusion, the Rhesus. The determination of the Rh antigens is often performed in conjunction with the determination of the ABO antigens and it is required before any blood transfusion. The Rh system is characterized by the presence or absence of a protein (D antigen known as Rh) on the surface of the red blood cells. In this way, an individual is Rhpositive (or Rh+) if he or she has the Rh antigen (D antigen) in their red blood cells, and it is considered Rh-negative (or Rh-) if he or she does not have the Rh antigen in their red blood cells. Rh-negative individuals, receiving a blood transfusion from an Rh-positive individual, will have the Rh antigen stimulated, and consequently, will produce Rh antibodies. Thus, if the same Rh-negative individuals require another transfusion and receive this new blood transfusion, a Rh-positive type will trigger up a transfusion reaction, caused by the Rh antibodies that the receiver already possesses [19]. Thus, the Rh-negative individuals can receive blood from Rh-negative individuals [1,19,33]. On the other hand, Rh-positive individuals can receive blood from Rh-positive, or Rh-negative individuals [1.19.33].

There are many other classification systems of blood types that have been identified in human blood, for example, Kell (K), Lewis (Le), MN, Duffy, Kidd P, and Lutheran [19], [21,32]. Although these systems are less frequent in the population and induce the formation of antibodies to a significant lower level of intensity in comparison to the ABO and Rh systems they cause minor consequences in terms of transfusion reactions [34,35].

#### 3. Material and methods

This section presents the specifications of the prototype. The prototype is intended to mix the blood and the reagents, to perform image processing – using the respective algorithms – and to obtain results automatically. This final step is performed using the software application interface used to operate with the prototype, the classification algorithms based on machine learning to classify the occurrence of agglutination, and the deterministic classification algorithm used to classify the result of the ABO and Rh tests.

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