Flow Analyzer for Blood Pump

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ABSTRACT

Medical equipment that supports life, relieves diseases, and overcomes disabilities can also cause damage and death due to operational failures, user failures, and misuse. Hemodialysis machines include roller pumps that control the flow of blood, and these pumps have to be calibrated accurately to ensure they are working properly. This article describes the development of a low-cost, open source prototype that automates the flow analysis (measurement and recording) of the blood pumps in hemodialysis machines. Being able to accurately inspect the machine’s operation improves the quality and safety of its use. Through this technology (this process automation), it is believed equipment downtime and total costs will be reduced.

This device has a system that collects data in real time, generated by the blood pump dialysis. Mathematical calculations are used to present flow information, including the standard deviation of the measurement (which is reported at the end of the test in an objective and simple way. Through a software and human machine interface (HMI), the test can be monitored and generate a report that contains the name and model of the equipment, the quantitative results of the flows, and the standard deviations of the measurements. The device can be used by clinical engineering teams in preventive maintenance and after corrective maintenance, as a control practice, making the calibration process easier and more cost-effective.

Keywords – Hemodialysis, Quality Control, Biomedical Analyzer, Arduino.

INTRODUCTION

Renal insufficiency occurs when the kidneys are unable to function properly.1 Hemodialysis is performed from a venous access allowing high blood flow. The blood is transported through an extracorporeal circulation system to a capillary filter, where it is purified and then returned to the body. It is usually performed three times a week, for an interval of three to four hours.2 Hemodialysis is susceptible to adverse events (AE) since it involves several risk factors, such as complications of invasive procedures, the use of complex equipment, critical patients, high patient turnover, and the administration of potentially dangerous drugs.3

The increasing use of hemodialysis worldwide is worrying specialists, researchers, managers, and health professionals. Data from the World Health Organization indicate that, annnually, tens of millions of people worldwide suffer disabling injuries or death due to AEs following hemodialysis.4

Medical equipment that supports life, relieves diseases, and overcomes disabilities can also cause damage and death due to operational failures, user failures, and misuse.5 Hemodialysis machines include roller pumps that control the flow of blood. The pumps should contain various alarms and other devices to ensure patient safety. Specific calibration is an important step for the correct operation of the equipment because the volume infused is the main parameter of the pump. It is essential that the methodology used in calibration be adequate for the tests to be validated as failure to do so can cause complications, including phlebitis, venous spasm, and pulmonary edema.6 The tests involve two parts – a qualitative evaluation (consisting of visual inspection of the structural conditions of equipment, parts, modules, and accessories) and quantitative tests (consisting of measuring or simulation of the parameters and/or the biomedical magnitude of the equipment).7 Some trials are still done manually costing the process time-consuming and decreasing the availability of dialysis equipment in a busy center. The calibration of the rollers involves adjusting the distance between the roller and the rigid bed (occlusion).8 At present, to perform calibration of the blood pump assembly, a precision scale, a graduated glass, and a digital timer are used, all of them traceable. Among the restrictions of this method are the uncertainties generated by the technical measurement process itself and the delay to carry out the measurement.9

The main objective of this work is to develop a flow measurement device for blood pumps of hemodialysis machines. Whereas flows generated by hemodialysis machines are greater than 1200 mL/h (maximum flow measured by the analyzers present in the market). The specific objectives to be achieved are (a) improving the process of inspecting the operation of the device, (b) reducing equipment downtime, (c) reducing costs related to the process of inspecting and testing quantitatively the equipment, and (d) improving the quality and safety of equipment use. For this development of the process automation, open source devices will be used, reducing the cost of the process.

METHODS

Method Flow

Figure 1 shows the flow of the steps followed for the development of this work. With the data specified, calculated, modeled, and simulated, the prototype was designed, developed, and tested.

Initially a group of studies was organized to evaluate possible solutions for a low-cost prototype for the blood pump flow analyzer. Several follow-ups were conducted at the hemodialysis center, along with the nursing group to measure the real complications of the conventional hemodialysis therapy. As shown by the flowchart if Figure 1, the other steps are described below.

Figure 1: Flow of the working method.

In order to perform this stage, three calculations were used: one to generate the flow, another to generate the volume, and a third to determine the standard deviation, within the limits of the processor and the requirements to analyze the blood pump flow, according to the following equations:
Conversions

Through the equations, Tables 1, 2, and 3 were developed with parameters for program development and report generator. The largest number of variables of the circular constant or Ludolph number (called “π”, being \[\pi = 3.14159265\]) was used to obtain the most accurate number possible.

\[
P = \frac{v}{hr}^2 \quad (1)
\]

\[
Q = \frac{volume}{time} \quad (2)
\]

\[
S = \sqrt{\frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n - 1}} \quad (3)
\]

### Programming

At this stage the Arduino platform was programmed (Figure 2), with a C language principle. Based on Tables 1 and 2, the volume and flow were described in the program. After this stage, the ultrasound sensor signal was programmed, making it a height meter to detect the volume of water and the valve, as a mechanism for releasing the water from the container in order to keep the blood pump always on, without overflowing the graduated container. The maximum level of volume was limited to 800 mL, and the minimum was 50 mL for the beginning of the readings.

![Electronic diagram of the circuit with the Arduino platform.](image)

This table represents the analysis of a flow of 50 mL/minute.

<table>
<thead>
<tr>
<th>Reading Numbers</th>
<th>Flow (mL/min)</th>
<th>Standard Deviation (mL/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>51</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>49</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>51</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>49</td>
<td></td>
</tr>
</tbody>
</table>

### MATERIALS

**Peripherals**

- **Installation** – The system used a selector switch.
- **Power Supply**
  - Standard 12 V, 2.3A, real power of 500 Watts, efficiency > 70%, TBF of 100,000 hours, 25°C, internal protection against OVP / OCP / SCP short circuit, AC input with manual switching 110 / 220 V, low acoustic noise, cables with protective cover, thermal cooling control system, 120 mm silent fan, technical standards IEC60950 (electrical safety), IEC61000 (electromagnetic safety) and On / Off switch.

**Relay**

- NA/NF of 5V.

**Valve**

- Valve with 12V solenoid.

**Mechanical Assembly**

- A cylindrical container was used as a reservoir, graduated with a total volume of 1000 mL.

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**TABLE 1. Conversion – Relation between Height (cm) and Volume (mL) in the Recipient**

<table>
<thead>
<tr>
<th>Direct Reading Container (mL)</th>
<th>Direct Reading Height (cm)</th>
<th>Calculated Volume (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>50</td>
<td>0.63665</td>
<td>50.00237407</td>
</tr>
<tr>
<td>100</td>
<td>1.2733</td>
<td>100.0047491</td>
</tr>
<tr>
<td>150</td>
<td>1.90995</td>
<td>150.0071222</td>
</tr>
<tr>
<td>200</td>
<td>2.5466</td>
<td>200.0094963</td>
</tr>
<tr>
<td>250</td>
<td>3.18325</td>
<td>250.0118784</td>
</tr>
<tr>
<td>300</td>
<td>3.8199</td>
<td>300.0142444</td>
</tr>
</tbody>
</table>

**TABLE 2. Conversion – Relation between Volume (mL) and the Time (minute)**

<table>
<thead>
<tr>
<th>Volume (mL)</th>
<th>Time (minutes)</th>
<th>Flow (mL/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>50</td>
<td>1</td>
<td>50</td>
</tr>
<tr>
<td>300</td>
<td>6</td>
<td>50</td>
</tr>
<tr>
<td>600</td>
<td>12</td>
<td>50</td>
</tr>
</tbody>
</table>

**TABLE 3. Conversion – Relation between Flow Readings and the Standard Deviation of the Readings Performed in the Range of 50 mL/Minute**

\[
(3) \, S = \sqrt{\frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n - 1}}
\]
Flange
A flange of ½ inch was attached to the bottom of the container for the water outlet.

Connector
A connector with the same diameter of the extender used in the conventional hemodialysis kit was installed for liquid inflow into the container.

RESULTS
To obtain the final results of the electronic part, the circuit was assembled. After the connection of the ultrasound sensor to the valve in the Arduino platform, four tests were performed and the analyzer responded satisfactorily. The final report is shown in Figure 3.

To obtain the final results of the mechanical part, the set was assembled as shown in Figure 4. After assembly of all electronic and mechanical parts, four tests were performed. With the design mounted, the set responded satisfactorily as shown in Figure 5.

CONCLUSIONS
Tools and support devices in the analysis and simulation of biomedical information are of great value in mitigating the risks related to the use of biomedical devices.

This article describes the development of an automated blood flow analyzer prototype to improve quality standards in the tests performed by clinical engineering services on hemodialysis machines. This prototype was found to reduce equipment downtime, reduce costs related to the testing process, and increase the safety of therapy with hospital devices that use blood pumps.

CONFLICT OF INTEREST
The authors declare that they have no conflict of interest.

REFERENCES