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An Automated Locking System to Prevent Backflow of Blood in an Intravenous Setup

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6 Abstract

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Intravenous (IV) therapy is a standard method of treatment in hospitals and clinics. However, 7 the intravenous infusion system has its drawbacks, one of them being the reverse flow of blood 8 back into the IV tube. The difference in pressure between the drip chamber and the venous 9 pressure causes the reverse flow. To address the above issue, hospitals use a blood pressure 10 cuff tied on the same arm where the infusion is given and, this cuff is inflated when backflow 11 occurs. However, this technique requires constant monitoring which is difficult when the 12 number of patients have to be monitored simultaneously. Although several automatic systems 13 have been developed to make the monitoring of intravenous infusions easier for both clinicians 14 and patients alike, there hasn?t been a system specifically designed to address this issue by 15 locking the tube. In this paper, we propose a valve-controlled locking system aimed at 16 preventing backflow using a load cell, a Hx711 amplifier module, a microprocessor and a 17 solenoid valve. This system is simple and cost-effective making it accessible even in poor 18

¹⁹ resource locations

20

21 Index terms— intravenous tube, drip chamber, backflow, load cell, solenoidal valve, automatic locking

²² 1 Introduction

ntravenous infusion is a form of therapy where fluids are infused into the body through the veins [1]. It is the standard method of treatment for individuals in whom food or medication cannot be administered orally. It is commonly used in chemotherapy, to reduce electrolyte imbalance to manage dehydration, fever and anemia [1], [2]. It is usually administered in the upper limbs due to an increased risk of thrombophlebitis during line placement in the lower limbs [3].

An intravenous (IV) setup consists of drip bottle, drip chamber, a capillary tube and a roller clamp. The drip 28 bottle is suspended from a stand at a height from the patient. The drip chamber is connected to the bottle at its 29 mouth. The roller clamp facilitates regulation of flow rate which is measured in drops per unit time. The fluid 30 in the drip chamber reaches the patients' vein as a result of the pressure difference between the drip chamber 31 and the patients' venous pressure [2], [4]. Once the volume of liquid in the bottle goes below a certain level, the 32 pressure is reversed causing backflow of blood into the capillary tube which has several adverse effects such as 33 blockage of tube, loss of blood, swelling, infection, hypothermia [5] and blood leakage [6]. Another severe effect 34 is air embolism [7] which can result in reduced cardiac output and in extreme cases cause death. 35

To prevent backflow, a manual method is being adapted in hospitals wherein a blood pressure cuff is tied on the upper arm and the catheter is passed beneath the cuff. The cuff is inflated when necessary, causing constriction of the lumen thus preventing backflow [8]. Although this method is quite simple and has not been proven to have any adverse effects, it requires constant monitoring by clinicians. Apart from backflow, intravenous therapy also requires tremendous effort on the part of the nurses not to mention continuous surveillance of the patients' status [9] which is difficult to do in poor resource locations.

In recent years, several methods [1], [2], [4][5][6][7][8][9][10][11][12][13][14][15][16][17]have been developed to make the process of monitoring intravenous infusion easier both for the patients and clinicians. These include alarm-based systems [1], [2], [5], [10], warning systems based on RFID technology [9], [11], optical detection [12],oneway valves [13], [14], flow sensors [15] and wireless sensors [16], [17]. Although several similar techniques
have been developed, none of them are aimed at prevention of backflow [5]. In this paper, we have proposed an
automated locking system which effectively prevents the backflow of blood into the catheter.

48 **2** II.

49 **3** Literature Survey

Several studies have been conducted and techniques developed to make the management of intravenous infusions easier. Across the studies, the various methods that have been used are listed below: Several studies [1], [2], [5], [10] have proposed an intravenous infusion monitoring and alarm-based system. Jianwen et al. used a photoelectric sensor technology and signal processing system to display and monitor the velocity of the fluid and also to indicate the blockage or end of an infusion process using an alarm. The hardware system consists of an infrared detection unit, SCM processing unit, data display module, sound and light alarm module, the locking module and wireless communication modules [10], [11].

In a study conducted by Shelishya et al., the system consists of slotted interrupter modules which are IR sensors used to monitor the flow of fluid in an IV tube. The sensor output is then given to an analog to digital convertor. This ADC output is then fetched by a microcontroller which is programmed to activate a voice module to alert the nurse on the end or blockage of an infusion process [5], [11].

Bhavasaar et al. emphasize intravenous liquid monitoring and alarm system using load cell as well as heart beat sensors. This method lowers the chance of heart attacks and reduces the complications in IV therapy by monitoring the level of the liquid in the IV bag when the level drops below the set point and by sensing air bubbles formed in the catheter [1], [11].

Raghavendra et al. designed a system for detecting variations in light transmission between a LED and a photodiode placed around the drip chamber. This device displays the drip flow rate and also has an alarm system which indicates the deviation from the pre-set value [2], [11].

⁶⁸ 4 b) RFID based systems

RFID system uses tracker tag system, these tags consist of electronically stored information and the passive tag 69 collects information from the nearby available RFID reader. In this technique the major components are load cell 70 of s-type, drip bag weight scale, RFID/NFC tag reader, 6502microcontroller system. The load cell transforms 71 the tension pulled by a drip bag, to weak electrical signal. Then the electrical signal is amplified and is filled 72 into a 16-bit A/D converter. Finally, the tension is converted into 2-byte digital weight data. The two-byte data 73 and five-byte RFIF data are packed as a data packet which is transmitted via UDP protocol to a data collector 74 module of IV infusion monitoring system [9]. The RFID tag is designed and attached on the bag of intravenous 75 drip. The tag is disabled when the bag is not empty because liquid contained [11]. 76

Sometimes LAN (Local Area Network) has been used in the process of data transmission. Active tags have
 local power source and it may operate hundreds of meters away from the RFID reader [12].

⁷⁹ 5 c) Optical detection

Here the system to be monitored is stimulated through an appropriate electromagnetic signal, typically a steplike voltage pulse, which is propagated through a probe, any impedance variation will cause the partial reflection of the propagating signal through a probe. Any impedance variation will cause the partial reflection of the propagating signal. The analysis of the reflection coefficient in time-domain, ?, allows the retrieval of the dielectric characteristics of the material under test, as well as of its quantitative parameters, such as in the case of the level of liquid materials [11], [13].

While considering the case of the liquid sample having a certain level, at the air-to-liquid interface an impedance chance occurs, due to the difference in dielectric permittivity. Therefore, the measured reflection coefficient shows a significant variation which may be used to individuate the air to liquid interface. Here the non-invasive probe is made of two strip electrodes, attached on an external surface of a container in which the medical liquid is contained. The ad-hoc probe configuration was realized through two adhesive copper strips with a width of 3 mm and a mutual distance of 3 mm [11], [13].

$_{92}$ 6 d) Flow sensors

The piezoresistive flow rate sensor inspired by the hair cell sensor found in the fish lateral line system has been composed and fabricated. The sensor has been bonded with a 3D printed fixture and they have been integrated on an intravenous tube. The responses of the sensor with respect to flow rates between 100Ml/h and 500 mL/h are noted. The flow rate has been tested using an experimental set up and it is controlled by peristaltic pump. The sensor shows both transient phase and stable phase responses [11], [16].

⁹⁸ 7 e) One-way valves

99 One-way values or non-return values (NRV's) are values that are used across several medical devices as a means 100 to prevent backflow in intravenous infusions and as a means of preventing contamination of the patients' fluids with the infusion fluids [14], [15]. These valves are specially designed allow only a designated direction of flow (DDF) [15] and can usually withstand high levels of reverse pressure before failing [14]. However, two studies [14], [15] conducted on these valves have indicated that they cannot be relied upon as a means of prevention of backflow or as infection control.

Ellger et al. [15] conducted a study on five different models of NRVs and tested them for rising levels of 105 pressure against DDF and migration of microorganisms proximal to the valve. As an outcome of the study, 106 40% of the NRVs' resulted in backflow in instance of rising pressure against DDF and 30% of samples showed 107 migration of micro-organisms near the valve. It was thereby concluded that NRV's are not a reliable method 108 of prevention of backflow or contamination of fluids. Another study conducted by Nandy et al. [14] to test the 109 levels of cross-contamination in one-way valves used 5 models of valves against3 different infusions passed against 110 the direction of flow. Leakage occurred in several models of valves against direction of flow. The conclusion was 111 that one-way valves are not reliable for prevention of contamination in case of backflow [11]. Wireless sensors 112 have been incorporated into monitoring systems for intravenous infusion monitoring. Zhang et al. [18] developed 113 a monitoring system which involved a monitoring sensor which was incorporated at an end of the infusion tube. 114 The sensor collects signals on the progress of the infusion. The sink node is deployed at a PC in the nurses' 115 station from where the infusion status can be monitored. The monitor software on the PC is used to generate 116 117 alarms and to process signals. It also provides information on the medicine administered, the volume, the drop 118 velocity [11].

Bustamante et al. [17] devised a system to detect any occlusions in the catheter or to detect when the catheter is empty and reduces the need for clinical intervention. It consists of a sensor, a radio module for low consumption, a feeding module to give an alert in case of low battery and a microprocessor. The sensor used is an optical sensor which is used to detect the dripping of fluid in the tube. The microprocessor receives the signal from the sensor and determines if the infusion is dripping or not and generates signals accordingly [11].

In the above studies, methods have been developed to facilitate easier monitoring but in all these systems, an alert is given whenever the flow rate varies or level of fluid in the reservoir falls below the desired range and a nurse has to manually rectify the issue. In this paper, we have discussed a valve-controlled locking system that automatically locks the IV tube based on a preset value of the bottle weight [11].

¹²⁸ 8 III. Valve-Controlled Locking System

The system has been designed in such a way to keep it as simple and cost-effective as possible. The setup primarily consists of a load cell, an amplifier module, a solenoid valve, and microcontroller. The load cell records the weight of the bottle, and the amplifier module strengthens the signal. The microcontroller reads the signal generated by the amplifier and accordingly controls the solenoid valve interfaced with it. The system design is as given in Figure 1.

The overall setup of the proposed system is as given in Figure 2. A load cell is present, from which the IV bottle is suspended. Based on the tension generated by it, the load cell produces an electric signal, which is equal to the weight of the IV bottle. Although, this signal is too feeble to be read by a microcontroller, hence it needs to be boosted. The amplification has been done with an Hx711 module, which is often used in tandem with a load cell. The amplified signal is then read by a microprocessor, which in turn controls a solenoid valve incorporated into the IV tubing. If the value read by the microcontroller goes below a critical point, the solenoid valve is turned on and locks the tube, thereby preventing backflow.

The software platform used is the Arduino IDE. A single control program monitors the weight of the IV bag. The flow of the program is as given in Figure 3 below. The output of Hx711 is monitored continuously in a loop. By default, the value of the solenoid pin is set to HIGH and is on. Once the weight of the bottle falls below the threshold point (e.g., 10 grams), the solenoid pin value is set to LOW and is switched off, thus effectively locking the IV tube.

¹⁴⁶ 9 a) Hardware description i. Load cell

To calculate the weight of the IV bottle, a load cell has been used. Here the load cell module has been used to convert it to analog data and sends it to the microcontroller [19]. A load cell is a sensor that can detect the amount of tension applied to it by the object suspended from it and generates an electric signal [20]. The capacity of load cells varies from 400g to 40 kg. For this system, to enable higher accuracy as far as the weight of the IV bottle/bag is concerned, a load cell of capacity 500g is used, as shown in Figure **??**.

In this system, the IV bottle is suspended from the load cell. The load cell has a parameter called calibration factor, which determines the stability and accuracy of the recorded measurements, and this value has to be set accordingly.

¹⁵⁵ 10 ii. Hx711 amplifier module

The Hx711 amplifier module, as shown in Figure ??, is used in combination with the load cell and integrates directly with the microcontroller.

The signal generated by the load cell is weak and cannot be read by a microcontroller directly. Hence, it requires amplification, and this is where the Hx711 module comes into the picture. It also plays the role of an analog-

digital converter, transforming the analog signal received from the two-weight sensors to a digital one, which is 160

sent to the microcontroller [21]. The amplifier module passes the strengthened signal to the microcontroller for 161

further processing. 162

iii. Microcontroller 11 163

The microcontroller is the integration point for all the hardware components and the controlling factor for the 164 valve. In this setup, the Arduino microcontroller is used for interfacing with the sensors and with the solenoid 165 valve, as shown in Figures 6 and 7. The Arduino Uno is a microcontroller board based on the ATmega328P 166 datasheet. It has almost 14 digital input/output pins (of which six can be utilized as PWM outputs), six analog 167 inputs, an ICSP header, a 16 MHz quartz crystal, a power jack, a USB connection and a reset button [8]. 168

The Arduino contains features that are needed to assist the microcontroller; simply connect it to a computer 169 with a USB cable or power it with an AC-to-DC adapter or battery to get started. It is easy to work with and 170 can interface with a variety of sensors and is costeffective when compared with other controllers. It also has a 171 reasonably low operating voltage and hence optimizes power consumption. The microcontroller reads the signal 172 from the amplifier module, which is equal to the weight of the IV bag. If the value decreases below a certain set 173 point, the microcontroller turns the solenoid valve on and locks the IV tube. 174

12iv. Solenoid valve 175

The solenoid valve is an electromechanical device that is used in this setup to lock the tube when the appropriate 176 situation arises. This valve has an electric coil known as solenoid with a ferromagnetic plunger. When the valve is 177 switched on, the electric current passing through the coil creates a magnetic field. The plunger is pulled towards 178 the center of the coil, causing it to open. When the solenoid valve is closed, it needs to be offered a lowered 179 current to maintain the valve pull-in state. This not only reduces energy consumption and calorific value but 180 also decreases the turn-off time and improves the turn-off response [22]. 181

Solenoid valves are available in operating voltages of 5, 12, and 24, 110, and 220 volts. For this system, a 182 12-volt valve has been used. The solenoid valve was chosen not only due to its' wide variety of applications in the 183 medical device industry such as in oxygen concentrators, drug-delivery systems, and dialysis machines to control 184 blood flow but also due to a list of other benefits including energy efficiency, lightweight and compact nature, 185

cost-effectiveness and reliability. 186

IV. 187

Result Analysis 13188

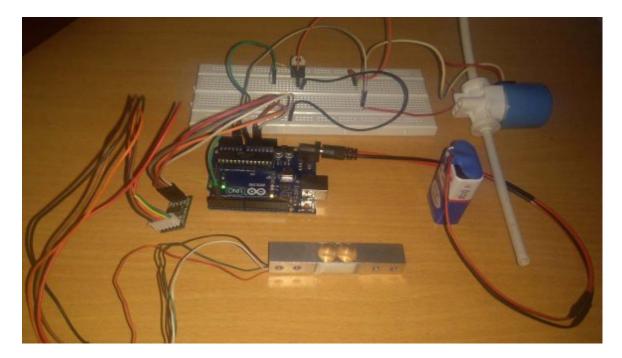
For the result analysis, several repeat tests have been done for this system. A random sample of the results 189 collected is shown in the table. Starting from the maximum volume condition, measurements related to the 190 decrease in the level of the liquid were also recorded. The set point for the weight of the IV bag was set at 35 191 grams for a bottle of capacity 500 ml. While the weight stays above the set point, the valve remains unlocked. 192 As soon as the weight of the IV bag falls below 35 grams, the valve locks the tube. The critical level at which the 193 tube is locked was set based on the levels of liquid used in previous studies [23], [24], [25], ??26] which focused 194 on raising an alarm to alert the nursing staff when the level of liquid went below a certain critical value. One 195 study [24] set the threshold value as 70 ml since the level of liquid at which the IV bag is replaced is between 196 50 to 100 ml. Setting such a midpoint value makes it easier for the clinician to replace the bag before backflow 197 occurs. Another study [25], the critical value was set at 50 ml for the first alert and in this was missed, another 198 alert was sent when the level of the liquid reached 30 ml. Another study ??26] conducted with an IV bottle of 199 capacity 500 ml sent an alert when the level dropped to 250 ml and an emergency alert when the level dropped 200 to 50 ml. However, the studies cited above focused primarily on sending alerts, but in this system, the focus is 201 on automatic locking. Hence, to minimize the wastage of liquids while simultaneously preventing backflow, the 202 critical level of the system was set at 35 grams. 203 V.

204

Conclusion 14205

The system proposed in this paper can be implemented in various settings, both in clinics as well at home. 206 The system is both simple and cost-effective. Although several techniques have been developed in the past, 207 these systems only address issues related to monitoring flow rate and raising the alarm in the event of any risk 208 of backflow, but none of them could effectively prevent the backflow of blood in the IV tube since no system 209 incorporated any kind of locking mechanism. Given the above observations, the implementation of this system 210 211 would result in a considerable improvement in the management of patients on intravenous therapy. The future 212 work involves the incorporation of an alarm system to indicate the status of the solenoid valve and a sensor to 213 control the rate of infusion along with application to notify the clinician when the IV bottle becomes empty and 214 to indicate variations in the set rate of infusion.

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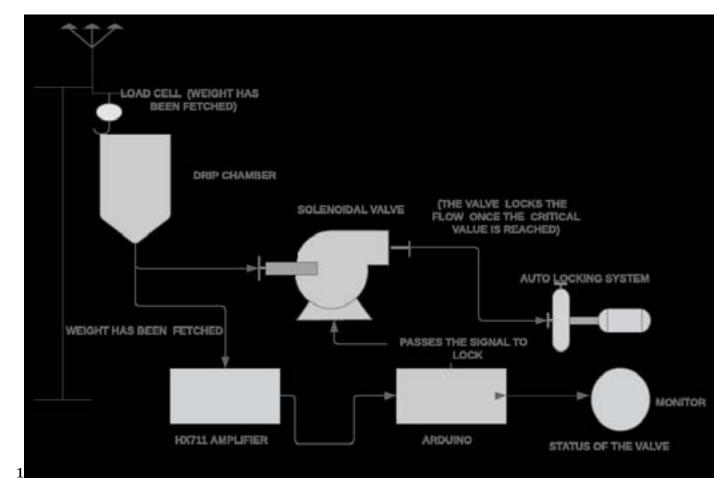


Figure 2: Figure 1 :

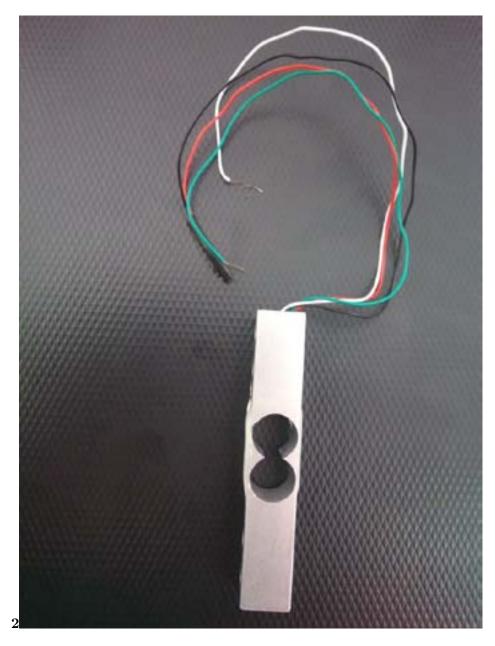


Figure 3: Figure 2 :

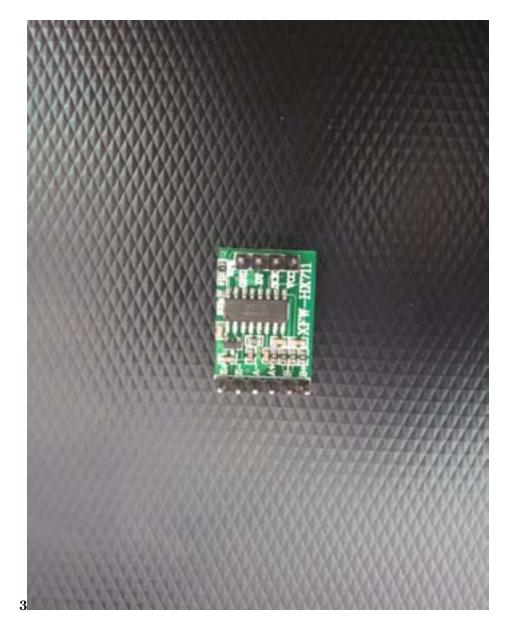


Figure 4: Figure 3 :

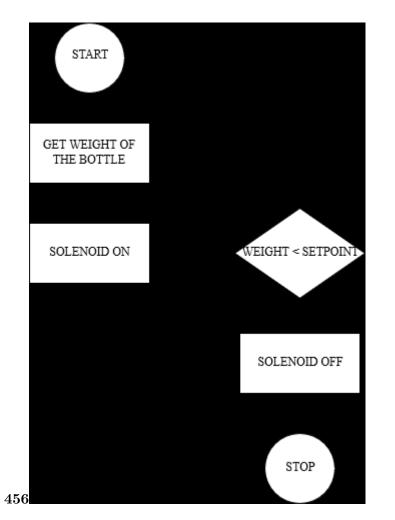


Figure 5: Figure 4 : Figure 5 : Figure 6 :

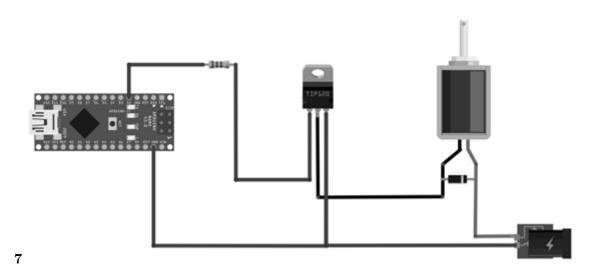


Figure 6: Figure 7 :

Level in IV bag	Recorded weight of	Solenoid
(ml)	the IV bag (g)	status
100	103.32	ON
75	77.86	ON
55	57.76	ON
35	37.44	ON
30	33.89	OFF
20	23.33	OFF
10	13.45	OFF
0	3.23	OFF

Figure 7: Table 1 :

14 CONCLUSION

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