Jurnal Teknokes
Multidisciplinary : Rapid Review : Open Access Journal **Vol. 15, No. 1, March 2022, pp. 14-20** **ISSN: 2407-896**

RESEARCH ARTICLE **OPEN ACCESS**

Manuscript received February 10, 2022; revised February 17, 2021; accepted March 1, 2022; date of publication March 20, 2022
Digital Object Identifier (DOI): https://doi.org/10.35882/teknokes.v15i1.3

How to cite Levana Forra Wakidi, Karina Maulidya S. P. and Maduka Nosike, "Electronic Infusion Flow Regulator Design with Occlusion Detection", Jurnal Teknokes, vol. 15, no. 1, pp. 14–20, March. 2022.

Electronic Infusion Flow Regulator Design with Occlusion Detection

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ABSTRACT Blockage of infusion fluid flow often occurs in the infusion pump is due to the presence of air bubbles that can trigger blockage of blood vessels and endanger the patient. This study aims to design an automatic infusion flow control device equipped with an occlusion detector. This module consists of Arduino Mega 2560, D.C. motor (stepper NEMA 17), optocoupler module, 4x4 keypad, and TFT. Infusion drops are detected by the optocoupler sensor. The microcontroller will process the detection results and send a command to the D.C. motor to move according to the settings entered. The unit of flow rate used in the module is ml/minute. An alarm will sound if a blockage occurs. After measuring using an IDA calibration tool with the brand Fluke type IDA 4 plus on the occlusion parameter, the average time was 41 seconds. The flow rate results had the largest deviation of 0.15 ml/minute at the time setting 6 hours and volume 500. At the same time, the smallest deviation was 0.12 ml/minute at a set time of 4 hours and a volume of 500 ml. The deviation in the measurement results is caused by several factors, namely the position of the hose, other light sources that affect the optocoupler sensor readings, and the amount of pressure in the infusion if the volume of fluid decreases. The design of this module is equipped with occlusion parameters to maintain patient safety from the risk of blockages in the flow of infusion fluids.

INDEX TERMS Infusion, Automatic, Occlusion, Optocoupler, DC Motor,

I. INTRODUCTION

The infusion pump is a device used to introduce a certain amount of fluid into the patient's body through the patient's veins continuously for a certain period [1]. The administration of intravenous fluids is limited according to the needs and conditions of the patient's body during the treatment period [2],[3]. So far, nurses have given intravenous fluids by manually counting the number of drops or volume so that there is the potential for dosing errors to occur [4]–[8]. The infusion pump helps nurses not to manually count the number of drops or the volume of infusion fluid, making it more efficient [9],[10]. Currently, many infusion pump designs have been made with various developments, including the addition of the automatic flow rate and volume adjustment feature by injecting liquid at a constant speed within a certain time [11]–[15]. This feature was created for patient safety and safety and error reduction, which is critical to improving patient care, with new technologies expected to contribute to these improvements while reducing costs and increasing efficiency of care in healthcare services [16],[17]. However, the use of this infusion flow regulator can cause some problems, such as blockage of the infusion line. Movement of the patient's hand can also cause blockage of blood vessels, if it occurs continuously without any protection, it will cause blood vessels to burst, which endanger the patient [18]–[20]. The occlusion parameter is needed to detect a blockage in the infusion line [21]–[25].

In 2002, K.K. Thariyan et. al. designed an infusion pump with a drip sensor [26]. This device applies the setting of many drops from the comparison of the volume of infusion fluid needed by the patient's body for a certain time multiplied by the volume of each drop. The device system uses an IR-LED as a transmitter and a phototransistor as a detector which is installed in a special room to detect falling drops. If no drip is detected or the infusion fluid runs out, an alarm will sound. This study discusses details about the design of the device, and the accuracy value is not yet known by comparing the application of the formula to the system with real measurements.

In 2009, P. Zhang, S. et al. [23] made a design for an infusion pump with an important parameter, namely the

occlusion pressure which functions to detect if occlusion occurs. This research has tested the infusion pump occlusion pressure according to the standard IEC 60601-2-24:1998/GB 9706.27-2005. This design system consists of sensors, acquisition cards, three-way and controlled by P.C. Simultaneously, the sampling rate can be set as needed and the test time can be recorded. This research also studies system characteristics such as linearity of parameter measurement, the effect of pump speed, and analysis of the use of different pumps. The system test results conclude that the system remains linear in a certain environment and the higher the pump speed, the faster the time to reach the occlusion condition. The system is proven to be effective in testing the infusion pump occlusion pressure and the pressure accuracy error meets the demand range of ± 1%. In this study, we have not tested the system using the Infuse Device Analyzer (IDA) Device and only compared it with standard system devices.

In 2020, Mohammed Arfan et. al. designed a system of intravenous (IV) drip rate control and monitoring for risk-free IV delivery. This study discusses the advantages and risks of IV infusion sets, the importance of IV infusion rates, existing infusion pumps, and disadvantages. The purpose of this research is to overcome the weaknesses of the previous infusion pump and to develop an IV infusion set that can monitor and control the drip set [27]. The author suggests the need for design development and innovation of IV drip sets for monitoring and controlling droplet rates as needed that are easy to use and cost-effective. Eric E. Smith et al. also developed Intelligent Infusion with Dedicated Pump for Infusion Safety [12]. Research is developing a safer infusion pump, Ivenix, Inc., committed to comprehensive usability engineering efforts has been tested for more than 400 hours of performance. As a result, the pump design includes risk controls to reduce potential use errors not available on today's pumps. This study has not explained the security of the system with occlusion parameters.

Based on the identification of the above conditions, the author wishes to design an automatic infusion flow control device equipped with an occlusion detector. The design uses Arduino Mega 2560 to run the entire system, processes sensor readings, and send motor commands (stepper NEMA 17) as the infusion fluid moves according to the settings entered. Optocoupler module as a sensor for blockage and drip of infusion fluid, 4x4 keypad for entering infusion fluid settings, and TFT LCD as a display device. The buzzer is added as an alarm in case of blockage. This system will provide early warning to nurses to take action if there is a blockage in the infusion tube so that the patient remains safe.

II. MATERIALS AND METHOD

A. EXPERIMENTAL SETUP

This study uses a comparison with Infusion Device Analyzer (IDA) (Merk Fluke Type 4 Plus) and uses the same volume setting of 500 ml and a time of 3, 4, 5, 6, and 7 hours. Data collection in the form of flow rate values was repeated 5 times and the results of occlusion were at a time setting of 7 hours and a volume of 500 ml.

1) MATERIALS AND TOOLS

The design of the tool in this study uses an Optocoupler sensor LM393 as a sensor to detect droplets in the drip chamber and the presence of blockages. A motor driver A4988 and a D.C. motor (NEMA 17 stepper) drive the IV fluid to flow into the hose. I.C. Microcontroller Mega 2560 PRO as a microcontroller to drive the roller clamp, sensor readings, process input data, and activate the buzzer. 4x4 keypad to enter the volume and timing of the IV fluid flow settings. TFT LCD as a display tool displays the volume and timing of intravenous fluid administration. The buzzer is added as an alarm in case of blockage. Our Digital Multimeter is used to measure the output analog voltage on the optocoupler sensor. The performance test of the tool design is compared with the Infusion Pump calibration device, namely the Infusion Device Analyzer (IDA) (Merk Fluke Type 4 Plus).

2) EXPERIMENT

In this study, after the design was completed, testing was carried out with an Infusion Device Analyzer (IDA) (Brand Fluke Type 4 Plus). In calibration, the output module is compared to the Infusion Device Analyzer (IDA) with the same volume setting of 500 ml and a time of 3, 4, 5, 6, and 7 hours. In each setting, the module outputs were calculated to validate the results of this study. Then the module is tested on the human body.

B. THE DIAGRAM BLOCK

In this study, the input component is the optocoupler sensor, and the keypad is in FIGURE 1. The keypad functions to determine the volume and time required to adjust the motor movement of the infusion clamp and will be displayed on a TFT. The optocoupler sensor serves to provide information on the presence of liquid in the drip chamber. The DC motor which is part of the system output functions to move the infusion clamp according to the desired number of drops per minute which previously used a motor driver to drive it and the buzzer will sound when occlusion occurs. Then the output in the form of flow rate (ml/min) is displayed on the TFT. FIGURE 1 shows, when the device is turned on it, starts with initialization for TFT. The user enters data in the form of the volume of infusion fluid to be used and the time required for the infusion fluid to run out on the TFT. The DC motor will work if the data has been entered and automatically move the roller clamp according to the settings used. Then the TFT will show the flow rate (flow) on the infusion. When an occlusion occurs, the D.C. motor moves the roller clamp to lock and the buzzer sounds. However, if occlusion does not occur, the D.C. motor will continue to work according to the settings entered.

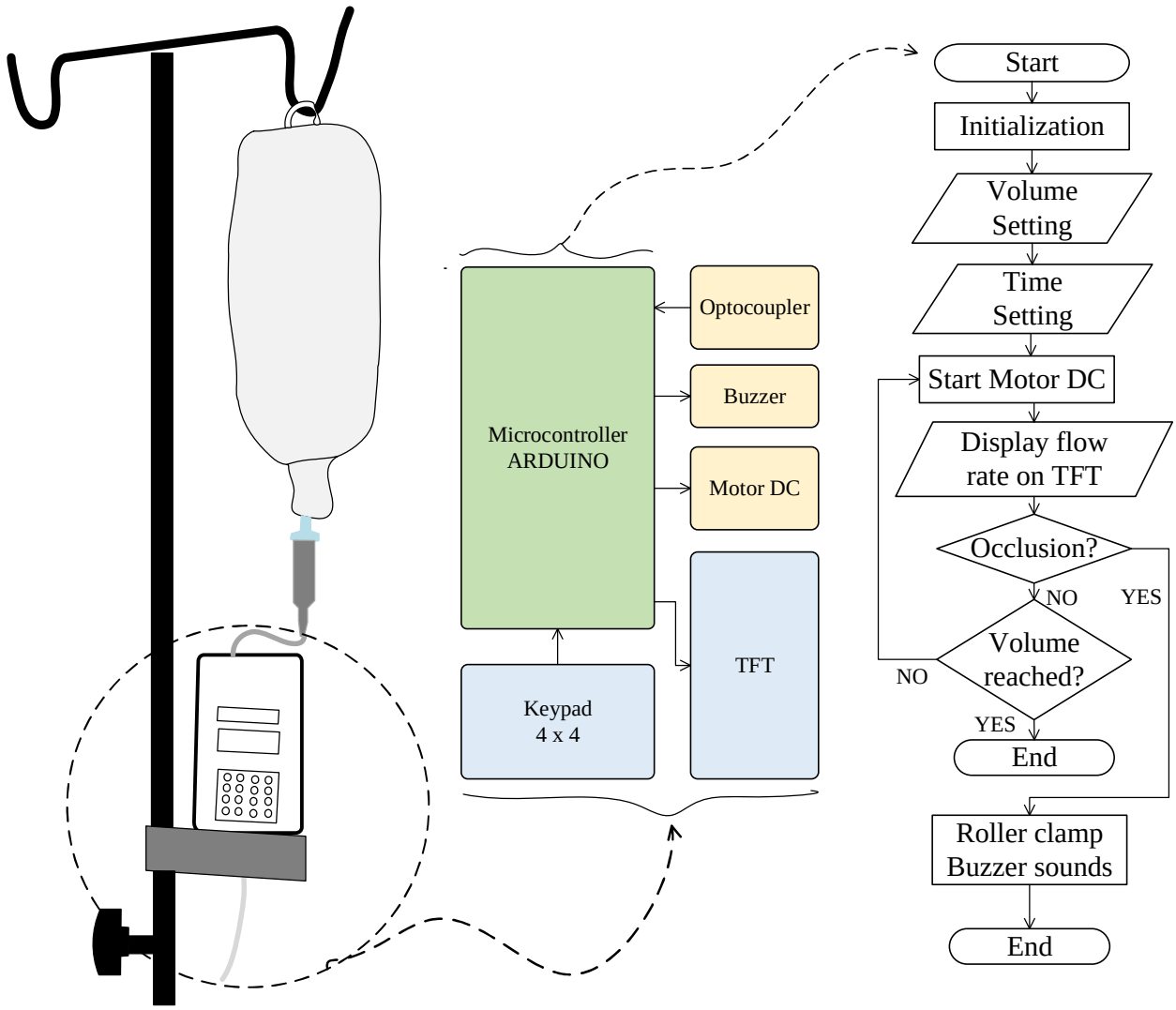

FIGURE 1. The diagram block and flowchart of the proposed design. Electronic Infusion Flow Regulator Design with Occlusion Detection

D. THE ANALOG CIRCUIT

The analog circuit consists of Motor Driver A4988 and NEMA 17 Stepper Motor. This circuit will work if the data from the sensor reading has been entered and automatically moves the roller clamp according to the volume and time settings used. The specifications of the required Motor Driver A4988 are as follow; the motor driver can drive for working voltage 8 to 35V and working current 2A (maximum). Furthermore, the size of modul is 15 mm x 20 mm. The input output digital for the driver is 3-5.5V. The Motor Driver A4988 circuit is a driver for controlling a bipolar stepper motor and complete micro-stepping motor driver with a built-in translator for easy operation and designed to operate bipolar stepper motors in full-, half-, quarter-, eighth-, and sixteenth-step modes, with an output drive capacity of up to 32 V and ±2 A [28]. The NEMA 17 stepper motor gets a supply D.C. voltage of 12 volts which is connected to the VMOT and GND pins. While VDD gets a supply voltage of 5 volts which is connected to the microcontroller. The motor driver has only two inputs DIR and STEP [29]. DIR serves to change the direction of rotation clockwise or counterclockwise which is connected to pin 15 on the Arduino. STEP functions to regulate the speed of the stepper motor by providing high and low signals that are connected to pin 14 on the Arduino. This driver has 5 different micro-step resolutions. The resolution settings of the motor rotation are MS1, MS2, and MS3 pins as shown in the table below:

TABLE 1 shows this circuit MS1, MS2 and MS3 are combined and get a voltage of 5 volts because the author uses full step micro-step mode. The limit switch in this circuit serves as an input to the microcontroller (pins 16 and 17) which will later be used to stop the stepper motor rotation.

TABLE 1
Stepper Motor Resolution Settings

MS1	MS2	MS3	Micro-step Resolution	Step Per-Resolution
LOW	LOW	LOW	Full Step	200
HIGH	LOW	LOW	Half Step	400
LOW	HIGH	LOW	Quarter Step	800
HIGH	HIGH	LOW	Eighth Step	1600
HIGH	HIGH	HIGH	Sixteenth Step	3200

III. RESULTS

The test measurement results for the first data with a time of 3 hours obtained an average of 2.9 ml, the error is the average difference between the module and the IDA device, which is 0.14, the percent error is the result of the error divided by the average IDA device multiplied by 100 and the result is 4.54%, then the standard deviation is 0.071. The second data with a time of 4 hours obtained an average of 2.0 ml, the error is the average difference between the module and the IDA device, which is 0.12, the percent error is the result of the error divided by the average IDA device multiplied by 100 and the result is 5.75%, then the standard deviation of 0.071. The third data with a time of 5 hours obtained an average of 1.68 ml, the error is the average difference between the module and the IDA device, which is 0.14, the percent error is the result of the error divided by the average IDA device multiplied by 100 and the result is 7.69%, then the standard deviation of 0.084.

The fourth data with a time of 6 hours obtained an average of 1.44 ml, the error is the average difference between the module and the IDA device, which is 0.15, the percent error is the result of the error divided by the average IDA device multiplied by 100 and the result is 9.32%, then the standard deviation of 0.055.

TABLE 2
Result Of Occlusion Value

IDA 4 Plus Fluke	
Time (s)	mmHg
56	103
36	107
35	104
38	106
41	108

The fourth data with a time of 7 hours obtained an average of 1.26 ml, the error is the average difference between the module and the IDA device, which is 0.13, the percent error is the result of the error divided by the average IDA device multiplied by 100 and the result is 9.35%, then the standard deviation of 0.055. The error above is caused by several factors, namely the flatness of the hose due to being stuck in the roller clamp for too long, sunlight affecting the reading of the optocoupler sensor, and the amount of pressure in the infusion due to reduced fluid. The results of the occlusion values in the module, when measured using the IDA Fluke 4 Plus calibration device, are shown in TABLE 2. These results indicate that occlusion did not occur until a predetermined time based on the IDA setting, the pressure of the infusion flow was relative and varied but did not show a significant change.

FIGURE 4. **Modul Testing Process with IDA**

A. THE MODUL DESIGN

The design of the Electronic Infusion Flow Regulator module with Occlusion Detection is shown in FIGURE 4 and 5. The module is given volume and time data settings using the keypad, where “A” is for volume input, “B” for time input, “C” for deleting, and “D” for start/stop of the device. The display in this module uses TFT. After setting the volume and time is complete, then press start, and the dc motor will move according to the program on the Arduino. The movement of the dc motor depends on the number of drops read by the optocoupler sensor. If the droplet reading of the optocoupler sensor is less than the desired setting, the dc motor will move to shift the roller clamp to reduce pressure. The result displayed on the TFT is the flow rate.

FIGURE 5. **Module Design**

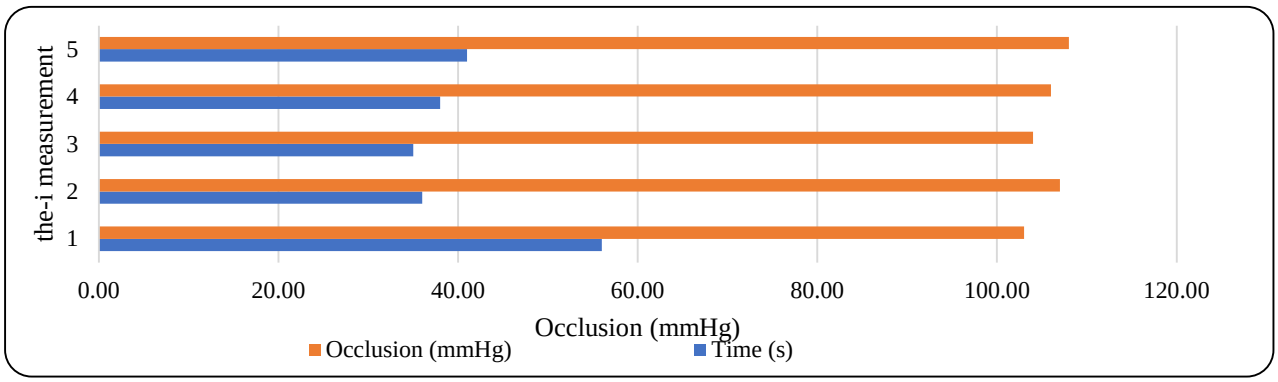

FIGURE 6. The occlusion ocurancy for several time and time location.

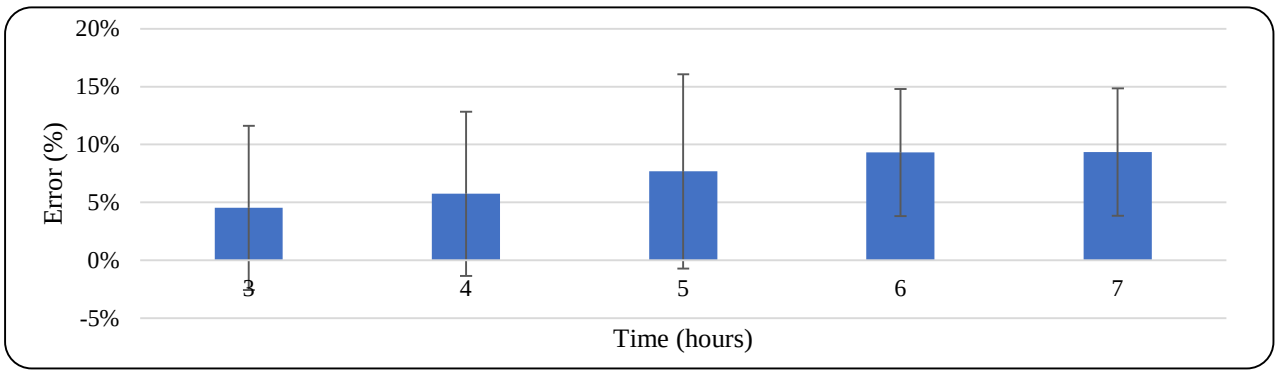

FIGURE 7. The error measurement for time setting

B. FLOW RATE MEASUREMENT AND TEST RESULTS

The measurements test on the module by measuring the output and comparing it with the results listed on the device display (FIGURE 6 and TABLE 3). In this measurement test, the volume used is 500 ml with a time of 3 until 7 hours. The test measurement results are shown in Table 3. the flow rate parameter with the highest time setting of 7 hours has an error of 0.13. While the lowest time of 3 hours has an error of 0.14. The biggest error is when setting 6 hours, which is 0.15 (FIGURE 7).

TABLE 3
Flow Rate Calculation Results on IDA 4 Plus Fluke

Hour	Error	Error (%)	StDev
3	0.14	4.54 %	0.071
4	0.12	5.75%	0.071
5	0.14	7.69%	0.084
6	0.15	9.32%	0.055
7	0.13	9.35%	0.055

C. RESULTS OF OCCLUSION MEASUREMENT AND TESTING ON THE FLUKE 4 PLUS INFUSION DEVICE ANALYZER (IDA) DEVICE

Table 4 shows the occlusion measurement and testing are carried out to determine whether the module can read if occlusion occurs. Data were collected using a volume setting of 500 ml and a time of 7 hours, and the module does not detect any occlusion.

D. RESULTS OF MEASUREMENT AND TESTING OF THE OPTOCOUPLER SENSOR MODULE

In testing and measuring the optocoupler sensor module measured at the sensor output, the red probe of the multimeter is connected to the output leg of the optocoupler sensor module, and the black probe of the multimeter is connected to the ground. Measurements were carried out under two conditions, namely when the optocoupler sensor module was exposed to water droplets and after being exposed to water droplets. After the drip the voltage is 4.68 and before the drip is 0.15 voltage.

TABLE 4
Occlusion Measurement Results Ida 4 Plus Fluke

Time (s)	Occlusion (mmHg)
56	103
36	107
35	104
38	106
41	108

IV. DISCUSSION

The module has been measured and calibrated using a Fluke brand IDA type IDA 4 plus device. The results of the flow

rate measurement at the volume setting of 500ml are as shown in Table 3. The largest deviation value is 0.15 ml/minute at the 6-hour setting and the smallest deviation is 0.12 ml/minute at the 4-hour setting. The results of the occlusion measurement as shown in table 4. show the meantime is 41 seconds and the pressure accuracy error value is less than ± 1% of the specified standard value. The variation in this value is caused by factors, namely the position of the hose tension due to being stuck in the roller clamp for too long, the sun or other light sources that can affect some optocoupler sensors, and the amount of pressure in the infusion due to liquid.

The performance of this module is also compared with other works, namely the research of K.K. Thariyan has not explained in detail the measurement results of the tool with a comparison tool and has not been equipped with an alarm in the event of occlusion [26]. From the results of measurements that have been carried out by this module, there is no display of flow rate results. The development of the tool still needs to increase the display of the flowrate results when reading by the sensor without having to wait for liquid drops and adding a reset mode by using the buttons on the keypad. And user can go directly to the volume and time settings without having to turn off the device and add a battery and turn it on so it doesn't turn off immediately when the power supply is unplugged. This system will provide early warning to nurses to take action if there is a blockage in the infusion tube so that the patient remains safe.

V. CONCLUSION

This study describes the development of an automatic infusion flow control device that is equipped with an occlusion detector. The results of the flow rate measurement at the volume setting of 500ml showed that the largest deviation value was 0.15 ml/minute at the 6-hour setting and the smallest deviation was 0.12 ml/minute at the 4-hour setting. The results of the occlusion measurement with an average time of 41 seconds. The development of the tool still needs to add to the display of the flowrate results directly when readings by the sensor without having to wait to stabilize the liquid drops and add a mode or reset button.

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