

Quality Assurance Measurement of Low Flow Rate Infusion Pumps Devices

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Abstract

Medical equipment in Intensive Care Unit (ICU) are high accurate and trusted devices. Infusion pump that uses low flow rate to infuse drugs (sometimes lower than 10 ml/h) into patients, is one of these accurate devices. The flow rate accuracy of the infusion pumps must be checked periodically. This study describes the implementation of a method to guarantee a high and low flow rate of delivered drugs accurately. This study followed the procedures, which are recommended by the ANSI/AAMI ID26 standard. The concluded results are compared to international approved analyzer, which is called ID4 plus analyzer. The obtained results show that the proposed method could be used to guarantee performance of infusion pumps with simple, accurate and low-cost advantages.

Keywords: Infusion pumps, low flow rate, quality assurance and ID4 analyzer.

1. INTRODUCTION

The most infusion pumps are used for continuous drug therapy to regulate drug concentration in blood[1]. Infusing drugs to patients with low flow rate must be accurate by using precise infusion or syringe pumps especially in case of infants[2],[3]. The infusion pump is set at a specific flow rate but over infusion or under infusion could harm patient under therapy[1], so it is necessary to make regular and scheduled performance test which is aimed to reduce the harm of dose deviation [4]. FDA (Food and Drug Administration) has initiated recalls of infusion devices depending on several reports which refer to failure of infusion pumps devices[5],[4]. Furthermore, the Biomedical Benchmark published by Emergency Care Research Institute (ECRI),introduces testing techniques and establishes intervals to assess flow accuracy[6].These procedures are recommended by ANSI/AAMI ID26 standard which includes particular requirements for the safety of infusion pumps and controllers[7],where it provides a detailed description of accuracy tests for drip-rate

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infusion controllers and infusion pumps. In pediatric, low flow rates often less than (10 ml/h) are used, that means any flow rate deviation could harm patient, so the infusion device performance must be accurate and not exceed recommended tolerance[8]. A recent study by J. Cebeiro[8] describes the implementation of a normalized method for infusion pump accuracy determination for low-flow delivery. It Depends on the concept of uncertainty where the error may either refer to the numerical parameters indicated or to a spurious distortion on a measurement process. The uncertainty specification may be referred to as precision[8],but this concept has some problems due to the liquid hydrostatic factors such as weight loss due to evaporation. Furthermore, other studies has developed a new methods to guarantee low flow rate infusion measurements considering precise, easy, repeatable and low cost [9]. The proposed method indicated for infusion pumps in ANSI/AAMI ID26 standard[7] where this method uses the number of liquid drops to calculate the low flow rate(1 ml/h) and the overall percentage of the flow rate error. Also, It can be used for evaluation the higher flow rates.The proposed method has some advantages such as the elimination of problems related to the liquid hydrostatic factors.

2. Method and Material

The proposed method given in this work depends on three main components which are the drop sensor, micro-controller and LCD as shown in Figure(1). This method depends on five steps to measure the flow rate of an infusion pump as the following:

- Recording the number of drops which come from a liquid container where this liquid is pulled by the Device Under Test (ICU).
- The reached volume and flow rate of liquid are calculated by drop sensor connected to Atmel 89C51 microcontroller as shown in Figure(1).
- When the drops full between the transmitter and receiver, The micro- controller pins are interrupted therefore the flow rates and volume are calculated.
- The result are taken and displayed by LCD.

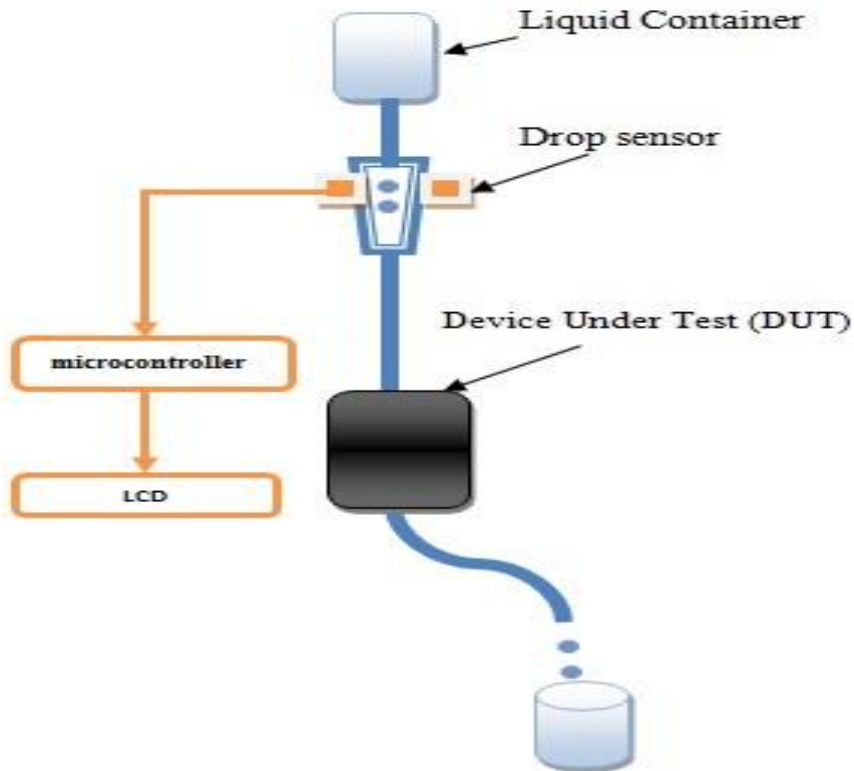
2.1 Hardware Implementation

As shown in Figure(1), the main components are described as follow:

- Drop sensor circuit: A drop sensor consists of light emitting diode (LED) and light depend resistor (LDR) work as light transmitter and light receiver respectively.
- Conditioning circuit: The operation amplifier (LM741) with low pass filter is used as a conditioning circuit.

Quality Assurance Measurement of Low Flow Rate Infusion Pumps Devices

- Micro controller: The microcontroller (AT89C51) 8 bit micro controller with 4K bytes memory is used. It has an enamors advantages like low power, high performance, highly-flexible and a powerful solution to many application.
- LCD: Is 6*12 LCD which displays 16 characters per line and there are 2 such line.
- ID4 plus analyzer :It provides an automated system for measuring the flow rate, volume. ID4 plus analyzer is an accurate device that evaluates the performance of the infusion pumps.



Figure(1): Block Diagram

2.2 Software Implementation

The micro controller code can calculate low flow rates less than 1ml/hour where the flowchart that describes micro controller code is shown in Fig(2).The volume is calculated as shown in the following equation:

$$RV = N * DS(\text{ml}) \quad (2.1)$$

Where :

RV is reached volume.
 N is the number of drops.
 DS is the drop size.
 The flow rate is calculated according to following equation:
 2.2

$$FR(\text{ml/hr}) = RV(\text{ml})/ET(\text{h}). \quad (2.2)$$

 Where :
 RV is reached volume.
 FR is the flow rate.
 ET is the elapsed time.

2.3 Performance Analysis

The performance and quality of the pump are assessed by an analysis graph, which comes from the main significant values of the recent flow rates. This process consists of two scenarios:

- The means are calculated by average of the recent and last values during the overall test time.
- The overall mean percentage of flow error is calculated by the following

Equation.2.3

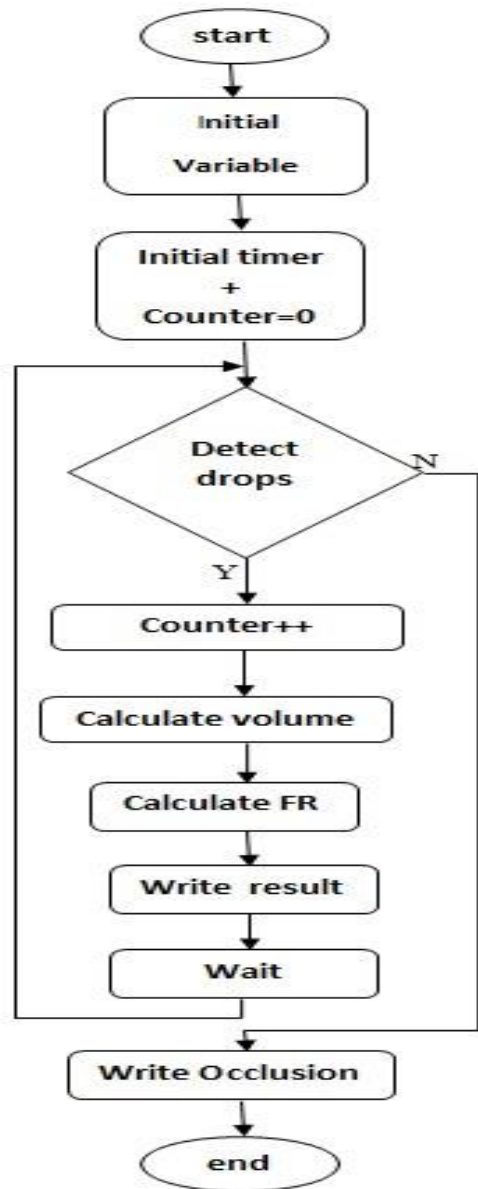
Where :

$$E = 100 * (MFR - SFR)/SFR \quad (2.3)$$

E is the overall mean percentage of flow error

MFR is the measured flow rate.

SFR is set the flow rate.



6

Figure(2): The Proposed Method

3. Results and Discussion

Practical scenarios are executed to measure the quality of an infusion pump. Figure(3) shows the results When flow rate of device under test(DUT)was set at (1 ml/hour),the two graphs indicate that there is no significant difference in the obtained results between the proposed method and ID4 analyzer during test time, but at the first(3 minutes) of the test, the proposed method reaches to the desired mean faster than the ID4 analyzer does, so this gives the proposed method advantage over ID4 analyzer that is better response than ID4 analyzer in case of the low flow rates. The obtained results at high flow rate where the (DUT) set at(5 ml/hour) and (18 ml/hour) respectively are shown in figures (4),(5).It is clear that there is no difference between the proposed method and ID4 analyzer results during test time. As shown in all above figures after one hour of test the results show no significant change in mean of flow rate at (1 ml/hour) and (5 ml/hour) whereas after half an hour of test, the results show there is no significant change in mean of flow rate at (18 ml/hour), so no need to waste longer time to verify the quality of (DUT). Table (1) shows a summary for the previous obtained results as a report of the proposed method and ID4 analyzer which show the last mean after one hour of test. Table(2)also shows the overall mean percentage of the flow error of the proposed method and ID4 analyzer(i.e. accuracy) and it clear the results obtained by proposed method and ID4 analyzer are very close.

Table (1): Summary Report

Comparison	Flow Mean (ml)		
DUT	1	5	18
The Proposed Analyzer	1.06	5.5	19
ID4 analyzer	1.1	5.7	19.14

Table (2):Overall Mean Percentage Flow Error

Comparison	Error(%)		
The Proposed Analyzer	6	10	5.2
ID4 Analyzer	10	14	6

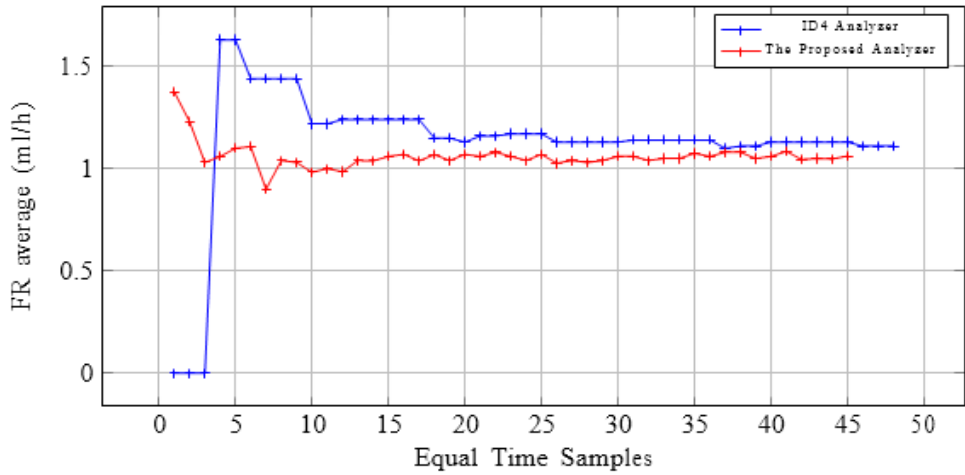


Figure 3: flow rate=1

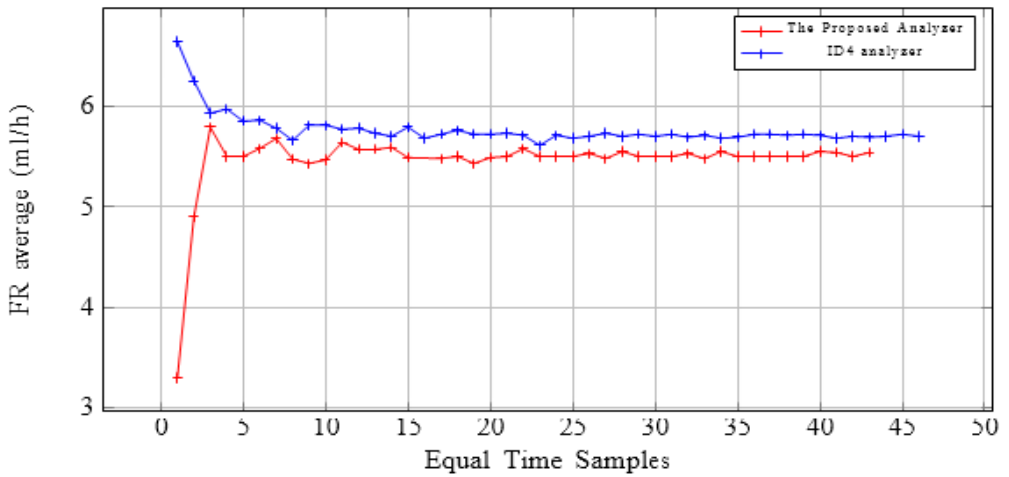


Figure 4: flow rate=5

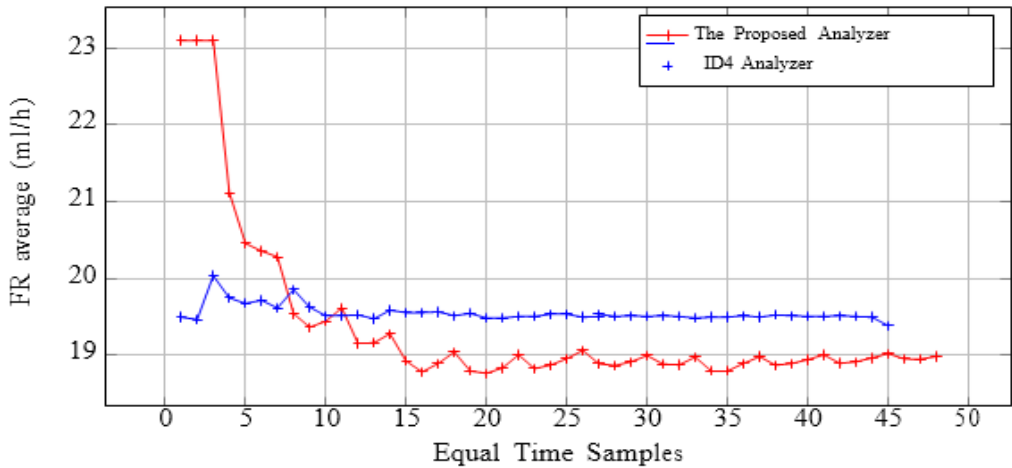


Figure 5: flow rate=18

4. Conclusion and Future Work

In this work, an alternative solution to test quality assurance of infusion pumps is proposed. The proposed method shows advantages such as easy of operation, demanding less test effort, low cost and it can perform the test even though the patient is under the treatment. The results show that the proposed method has more response at low flow rates than ID4 analyzer at the beginning of the test time. The proposed method results show there is no significant change in means of flow rates at(5 ml/hour) and lower after one hour of test so no need to waste longer of this time to verify the quality of Device Under Test (DUT).The proposed method also can be used for high flow rate evaluation. At flow rate (18 ml/hour) or above, the results show there is no significant change in means after half an hour of test, so no need to waste longer of this time to verify the quality of the Device Under Test (DUT).The liquid evaporation problem that appeared in the uncertainty methods and, liquid viscosity and all nearly the liquid hydrostatic factors are not found in this proposed method. In the future to improve this study, more than one infusion pump at the same time will be tested using better micro controller and also the graphical LCD could be used.

5. References

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