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Design of occlusion pressure testing system for infusion pump

Peng Zhang[1], Shu-Yi Wang[1], Chuan-Yi Yu[1], Min-Yan Zhang[1]

[1]School of Medical Instrument and Food Engineering, University of Shanghai for Science and Technology, Shanghai, China.
Email: zhangpeng3722@163.com

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ABSTRACT

Reliability of medical devices such as infusion pumps is extremely important because these devices are being used in patients who are in critical condition. Occlusion pressure, as an important parameter of infusion pumps, should be detected when an occlusion occurred. However, infusion pumps' occlusion pressure could not be tested and the performance of these pumps is not known to us. In order to test the occlusion pressure of infusion pump, a testing system has been put forward according to standards of IEC 60601-2-24:1998/ GB 9706.27-2005. The system is comprised of sensor, acquisition card, three-way tap and so on; this system is controlled by a PC. At the same time, sampling rate could be changed if necessary and test time could be recorded. And then the characteristics of this system were studied, such as linear, effects of pump rates and different pumps. The system remained linear in a given environment. The higher is the pump rate, the faster is the time to reach occlusion condition. The testing system has been proved to be effective in testing the occlusion pressure of infusion pumps and the accuracy error of pressure is content the demand of ±1% of range.

Keywords: Infusion Pump; Occlusion Pressure; Testing System

1. INTRODUCTION

Infusion pumps have been widely used in clinical practice, such as in intravenous infusion therapy to infuse fluids, medication or nutrients into patient's circulatory system and can produce quite high but controlled pressure so as to inject controlled amount of fluids, however, pressure values are different regarding to different pumps.

Nowadays, most infusion pumps have an occlusion pressure preset threshold, once the pressure of tubing, connecting to patients, exceeds the preset limit, the alarm of occurring occlusion will be active. Some infusion pumps adopt a method of speed administration, in this case, if fluid rate is zero during a certain time and the alarm of occlusion will be active. However, on the one hand, the pressure values of vascular are different regarding to different persons and the same person at different time. When an occlusion occurs along the delivery path, medication will not be delivered to patient but the pressure does not reach the preset pressure and the alarm will not be active. In this case, the pump can not only continue to operate normally, but it can display erroneous values about the infusion rate and accumulated volume. This incorrect record for the patient could lead to an improper analysis, which will cause injury to patient. The higher is occlusion pressure, the more serious is the injury, so the test of occlusion pressure is crucial to pumps [1]. On the other hand, the inaccurate infusion rates of infusion pumps could be generated if the pumps are not checked up after a long time usage. At last, some infusion pumps could be used to detect tissue extravagation [2]. At this moment, infusion pumps must be periodically tested to determine whether they are functioning properly [3,4].

A testing system of infusion pump occlusion pressure is designed to test an infusion pump and determine whether the pump is operating correctly.

At present, there are several products commercial availably in market; mostly they are designed by foreigners, such as IDA-4 Plus Infusion Pump Analyzer, Infutest Solo Infusion Pump Analyzer and so on. The former is designed by Fluke, it has a function of PCA (Patient Controlled Analgesia) Pumps Bolus measurement and testing four pumps at the same time; the latter is designed by Datrend Systems Inc. and there are other corporations to design infusion pump analyzers (tester) [5,6]. Though these devices have well performances, the price is high accordingly. At the same time, some of these devices are not designed rationally; one device is ruined for its first using, so we designed this simple but good performance testing system. But the most important point is that these devices are not designed followed the IEC 60601-2-24:1998 standard, so they can be not be used to test other infusion pumps and so on.

During our previous work, we have found that, if fluid speed is low in syringe pumps, in the curve of time-pressure, there exists and smooth phase liking a part of round and pressure values should be the in this phase. On this condition, we adopted a different method and got an elementary result, but this method was not satisfactory and would be ameliorated.

2. METHODS AND APPARATUS

2.1. Description of Apparatus

According to the standards of IEC 60601-2-24:1998 and GB 9706.27-2005, a test system is designed which is shown in **Figure 1**. This system is applied to infusion pumps, volumetric infusion pumps and syringe pumps [7,8].

The testing system can be divided into three parts according to their different functions.

Part 1: In this part, the aim is designed to provide infusion pumps to be tested; and infusion pumps provide the driving force for occlusion pressure. The administration set, which is medical tubing in this system, sets to 1 m.

Part 2: The aim is designed to simulate the occlusion in patient and collect the fluids. Occlusion is realized through the turning of three-way tap and then the signal of sensor is transmitted to the acquisition card. At the beginning of test, when the three-way tap is opened, fluids will be collected in the collecting vessel; if three-way tap is closed, occlusion pressure will be generated following the rigid tubing and then the pressure signal is transmitted to the pressure transducer. At the end of test, fluids will be collected in the collecting vessel.

Part 3: In this part, the interface between PC, running under Windows XP and sensor was realized through an RS-232 connection. The sampling rate is controlled by PC and software, which is basing on Visual C++ 6.0 platform. The signal, coming from sensor, is obtained by acquisition card, and then is transmitted to computer. After the further dealing and calculation of signals, the dealt signals could be displayed on monitor in the form of wave.

2.2. Measurements

The test is carried out using a test solution of ISO class Ⅲ water for medical use, under normal condition (20℃±2℃, 65%±5%RH (Relative humidity)). There are several steps to implement this apparatus [7,8]:

First: Connect all the joints and check the testing system. The rigid tubing between three-way tap and sensor should fill with water in advance. If the occlusion alarm threshold can be selected, set it to minimum. Then, set the appropriate pump rate and volume, then start it.

Second: Open the three-way tap (stopcock) and let fluids flows into the collecting vessel. Close the three-way tap (stopcock) when the internal liquid flow becomes steady and test the occlusion pressure alarm threshold, this threshold will be registered by computer, then collect fluids, which generated by the expand of medical tubing.

Third: If the occlusion alarm threshold can be selected, repeat the test with the occlusion pressure set to maximum.

Pressure sensor is an important part in testing system, and the accuracy and precision of sensor are influenced by actual environment, such as temperature, relatively humidity. So to ensure the accuracy of the testing result, pressure calibration of the testing system is necessary before testing infusion pumps.

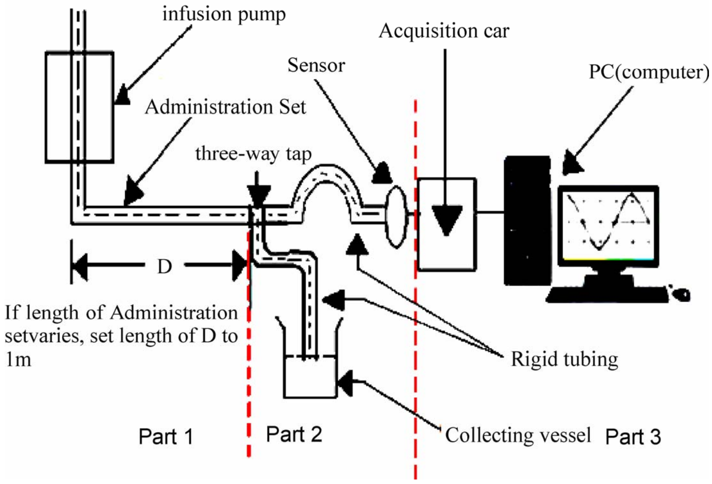

Figure 1. Structure of infusion pumps testing system.

Table 1. Relation between calibrator value and computer display value.

Calibrator display(KPa)	10.10	19.99	29.96	40.01	50.01	60.02	70.01	79.99	89.98	99.98
Computer display(V)	2.7309	2.9733	3.2176	3.4636	3.7087	3.9555	4.2012	4.4464	4.6906	4.9373
Results of expression(KPa)	10.13	19.99	29.92	39.96	49.95	60.01	70.01	80	89.96	99.99
error	0.03	0	0.04	0.05	0.06	0.01	0	0.01	0.02	0.01

Regarding to the Infusion Pump Analyzers mentioned before, the occlusion pressures are recorded once the pressure level is highest, at the same time the elapsed time is recorded [5,6]. In this testing system, the occlusion pressure and elapsed time are recorded, meanwhile, the delayed time, between the pressure reaches to the alarm threshold of infusion pump and the pump is not active, is recorded. The delayed time is also an important parameter though it is zero in some pumps. The real-time pressure wave could be displayed in monitor and could be reviewed and analyzed.

3. RESULTS

In this testing system, pressure calibrator of Fluke-718 30G was used, it can be used to calibrate pressure sensor and this testing system, its accuracy is ±0.05% of range and resolution is 0.01KPa [9].The performance of pressure sensor, under the same environment is summarized in **Table 1**. The unit of calibrator is KPa and computer display is V (voltage), computer display is the value of pressure signal, which has been magnified and filtered.

From the data results above, we can see that if the value of calibrator increases about 10KPa, the value of computer display increases about 0.24V correspondingly, so the performance of pressure sensor shows well linear.

Based on the relationship between calibrator value and computer display value, a line could be drawn. The relation between the display of computer and pressure calibrator is almost linear. The expressions were calculated with least squares approximation and they are: $y = 40.732x - 101.11$ and $y = -0.0392x^2 + 41.033x - 101.66$, respectively. The sign x is computer display which is obtained form acquisition card and the sign y is the value of calibrator. Since the model is almost linear, the primary output is proportional to the input signal, so the first expression is enough in this system. In our testing system, the range of pressure is 0-200KPa and the accuracy of testing system is ±1%, so the error is allowed basing on the linear expression.

Three different infusion pumps (ANGEL-AJ5800, YDBS-11A, and ATOM-P300) were tested under the infusion rate of 250ml/h and sampling rate was 1Hz. The performance of infusion pumps is shown in **Figure 2**.

4. DISCUSSION AND CONCLUSIONS

The lines in **Figure 2** are test results of the pumps and these tests were implemented under normal environment. From these results, firstly, a peak pressure (occlusion pressure) can be found, peak pressure of ATOM-P300 infusion pump, ANGEL-AJ5800 infusion pump and YBDS-11A infusion pump was 114.80KPa, 215.80KPa, and 165.1KPa respectively. Secondly, occlusion time (the time from occlusion to occlusion alarm) was 12s, 38s and 12s, respectively.

The different occlusion pressures between infusions pumps could be seen from the test results. ATOM-P300 infusion pump has a pressure sensor and the precision is high; ANGEL-AJ5800 infusion pump has a higher occlusion pressure value. Pressure of YBDS-11A is neither high nor low. In order to ensure the safety of patients, low occlusion pressure and occlusion time are necessary and pressure sensor is the better choice in fusion pumps. The occlusion pressure of usual infusion pumps is about 100KPa, and some new made infusion pumps is about 7PSI (48.265KPa) or even more lower. Occlusion pressure alarm of ATOM-P300 infusion pump is lower than YBDS-11A infusion pump and ANGEL-AJ5800， ATOM-P300 infusion pump can prevent patient from hurting much sooner than the latter if an occlusion happens.

The sensor is influenced by environment, especially by temperature. In order to ensure the accuracy of the

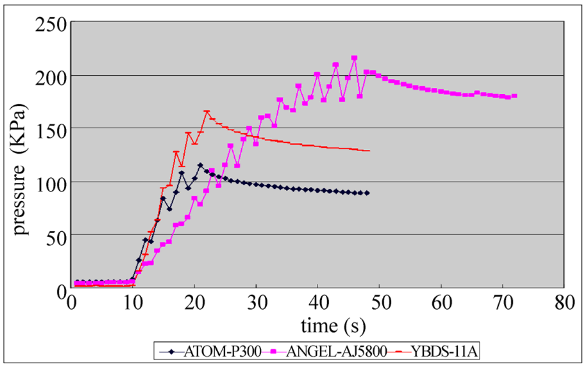

Figure 2. Relation between time and pressure of different pumps.

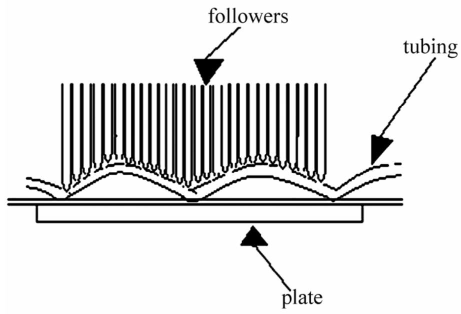

Figure 3. Structure of infusion pump.

test, calibration process should be implemented before performance, even in stable environment, calibration should be operated periodically.

Most infusion pumps are peristaltic, so the pressure is not stable. After a higher (lower) value, there is a lower (higher) value, as shown in **Figure 2**. That is determined by the structure of infusion pump, shown in **Figure 3**, so it is natural for the unstable pressure value.

We have mentioned that pressure curve of syringe pump is different to infusion pump; it is also determined by their structure.

In this study the infusion pump testing system is designed and its focus is detection of occlusion pressure. The results of infusion pump automatic detection system have verified that this method is efficient in different type of infusion pumps. The future research is concerned with these following topics.

1) Software should be perfect. The essential function could be achieved in present software, but many accessional functions should be achieved in the future. The friendly interface is necessary and the manual operation should be decrease to ensure the accuracy of the testing system.

2) Although the occlusion pressures of infusion pumps were recorded, the delayed time should be recorded by testing system automatically, through analyzing the obtained data results.

3) The system is influenced by environment, such as temperature，relative humidity, so more tests should be implemented to come to a much better relation between system and environment, which can be a reference for further tests.

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