

Design of Miniature Disposable Flow Sensors for Medical Applications

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Abstract: The demands in homecare in North America and Europe have required cost effective disposable flow sensors for avoiding cross contamination and other damages. Examples are the infusion pumps and personal ventilators. For the infusion pump applications, a miniature liquid flow sensor is required to handle the micro flow during the injection of the medicine so that a constant injection can ensure the patient with ultimate comfort and prevention of side effects. This application also requires micro-fluidic design for the flow range of 0-500mL/hr. A MEMS flow sensor designed with the extended range capability could be the choice for this purpose. In this paper we present the design and prototype of such a sensor. The MEMS flow sensor chip with calorimetric principle is separated from the control electronics and encapsulated into a medical plastic package where a pre-manufactured micro-fluidic channel provide the path for the medicine with the sensor placed at the sidewall of the pre-manufactured flow channel. The MEMS sensors that have excellent exchangeability make it possible for disposability of the entire plastic unit.

Keywords: MEMS flow sensor, Disposable flow sensor, Medical sensor

1. Introduction

With the ever growing population towards an aging society in today's world, the demands for efficient medication or homecare require new technologies to meet the challenges. In addition, current medication also pressures the requirements on dose accuracy, cost-effectiveness, process automation and contamination free approaches as well with the goals for patients' ultimate comfort. One of the fast growing homecare medications is the drug delivery by infusion therapy such as pain management, antibiotics delivery, hydration therapy, transfusion therapy and nutritional therapy.^[1-3] The equipments for the infusion therapy are various types of infusion pumps, often in the disposable configurations for the homecare, that deliver the specific amount of prescribed medication or nutrition fluids into patients from a container. The total market for the number of such devices is estimated to be about 2 billion US dollars with an annual shipment over 60 million units. Nevertheless, the current homecare infusion delivery system inherits some potential errors such as improper dose or dose rate, vein occlusion and air embolism. These problems do occur from time to time and it was estimated an annual cost over 50 billion US dollars in US alone,^[3] that was well over the equipment market itself.

As the current mechanical infusion pumps do not have any controls in dosing speed and the prevention of embolism is difficult to realize, development of a sensor for the purpose would be very valuable. In addition, one of the most important issues in homecare medication would be the minimization of contamination in addition to the cost as the end users may not have enough trainings or knowledge for the applications. Therefore the disposable capability would be very

critical. There are a quite few efforts for attacking these problems. Existing technology such as optical or ultrasonic can theoretically identify the air embolism problems while providing the measurement of the flow rate. The cost and bulk packages however make them infeasible for the homecare applications. ISSY^[3] developed a MEMS Coriolis flow sensor that can measure the mass flow rate as well as the drug density and has been applied for the drug flow monitor system. It also can differentiate the air embolism easily as the vibration frequency for air and liquid would be significantly different. However, as this measurement principle is based on the accuracy of the vibration frequency detection, the calibration process would not be a simple process even with the precise measurement of the fluid temperature simultaneously, which would be a cost barrier for the disposable applications. Sensirion^[4] has released a thermal mass flow sensor packaged on a glass substrate. The sensor has integrated the signal conditioning circuitry on a single microchips and the measurement of the mass flow is non-invasively through the wall of a flow channel inside a planar microfluidic substrate. It can also differentiate the air bubble and the liquid as the thermal conductivities of these two are substantially different. Although the non-invasive design provides excellent wetting free capability but it also add the requirement for precise fabrication restrictions and environmental stability, which adds more to the complexity in reduction of the final cost. In this paper, we present a simple MEMS thermal mass flow sensor and package that separate the circuitry from the sensing chip providing the feasibility and ultimate freedom for the disposable applications.

2. Sensor Design

2.1 MEMS Sensor Fabrication

Figure 1 shows the schematics view of the MEMS flow sensor discussed in the present study. The size of the mass flow sensor was above 2x2.3mm and it has four thermistors on each sensor. The thermistor A placed in proximity to the silicon substrate for the measurement of the environment temperature while the thermistor B is designed for detecting the changes in thermal conductivity of the fluid, such that the air-liquid alarm can be attested. The thermistor D is the micro-heater and thermistors C and C' are the upstream and downstream temperature sensor. The thermistors D-C-C' are the basic calorimetric flow measurement elements.

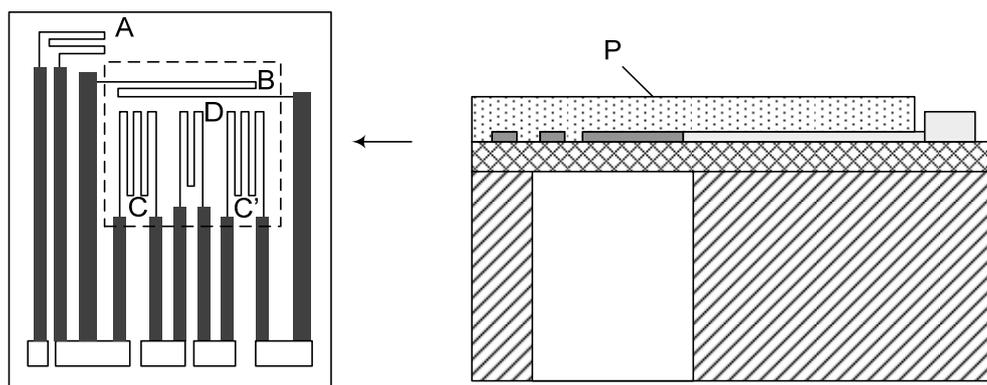


Fig. 1 Schematics of the top and side view of the MEMS sensor

The MEMS sensors were fabricated on silicon substrates. The low pressure chemical vapor deposition process was applied for deposition of 2 μm of low stress silicon nitride films as the sensor support. All the thermistors were made of platinum via e-gun evaporation. The thermal isolation cavity underneath the silicon nitride membrane was obtained by deep reactive ion

etching. To isolated the direct contact of the thermistors with the fluid, the sensor surface was protected with a low stress silicon nitride, P, as indicated in the figure, made by plasma enhanced chemical vapor deposition (PECVD) followed by a thermally conductive polymer surface passivation so that the pin-holes in the silicon nitride film by PECVD can be fully sealed from liquid penetration. In the MEMS fabrication process described above, only four photo-masks are required for the manufacture of the sensor chip. For the process on a six inch silicon wafer, a total of 3800 chips can be obtained and the typical yield is normally over 95%, which makes the sensor as the major component in the disposable package very affordable.

2.2 Sensor Package

For the infusion delivery system, the most common flow range is 0~500mL/hr^[2] which is close to the microfluidic domain. The measurable flow range for the MEMS thermal mass flow sensor is determined by the design of the flow sensor and the flow channel size. It is also important for the package design as the manufacturing cost must be taken into accounts for the disposable requirement. Figure 2 shows a concise package design (a) and the prototyped sensor picture (b). The package has a dimension about 10×12mm containing three components. The flow channel and inlet port is made on component A (A' is the view of the inner side) where the rectangular channel dimension was designed to be 1.2×2.8 mm to meet the flow range requirements. Component B is the mass flow sensor that would be placed into the cavity shown in the sensor holder (Component C). The outlet of the flow is at the Component C as shown in the figure. After wire bonding of the sensor connecting to the sensor holder, Component A is bonded with C either via an ultrasonic bonding or by medical compatible glue. The package is then ready to be connected with the control electronics in the infusion delivery system. Many medical compatible plastic materials can be selected depending on the specific applications. Among them, polycarbonate or polyphenylsulfone is commonly used and the final experimental prototype picture shown in Figure 2 is made by polyphenylsulfone. This simple package design pushes the cost to the lowest possible, and estimated in few tens of cents in volume, which turns the disposable medical sensor concept a reality.

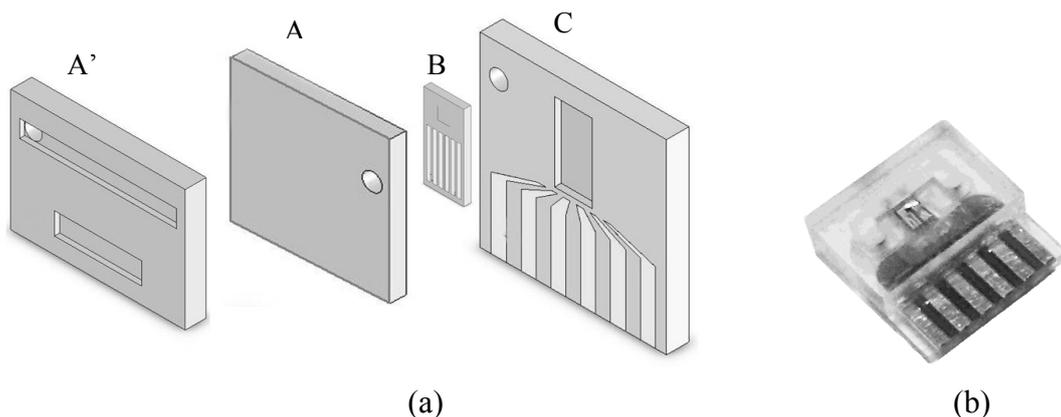


Fig. 2 Explosive view of the disposable sensor components (a); and the experimental final package with machined polyphenylsulfone plastics (b).

2.3 The Control Electronics

The disposable sensor control electronics can be an independent unit connecting to the main board for the infusion delivery system or integrated into the main board of such. The EEPROM can be used to store the historical data for tracing the usage. The board can communicate with the

system either via the digital RS232 interface or the analog voltage. The microcontroller shall not be necessary after integrated with the system. The whole electronic control units plus the power consumptions at the MEMS sensor can be as low as 0.5mW which allows portable applications with battery as the power source.

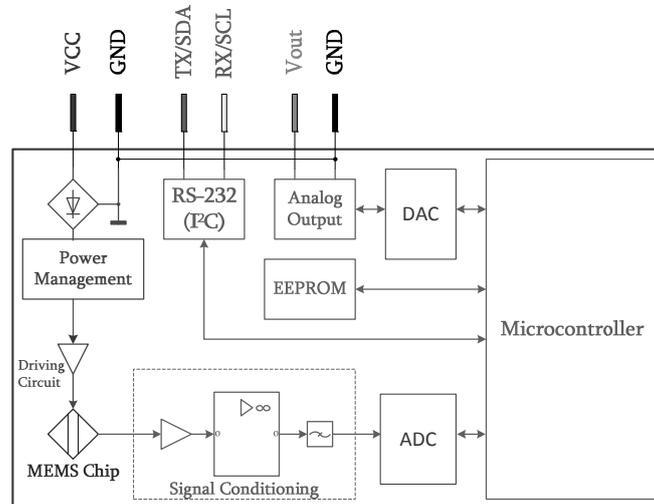


Fig. 3 Block diagram of the control unit

3. Test Results

3.1 Sensor Performance

The sensors were all calibrated by a Coriolis mass flow meter manufactured by Brooks Instrument (Model QMBC) with an uncertainty of $\pm 0.2\%$. The measured uncertainties for the meters are obtained by another independent QMBC mass flow meter that has the same uncertainty of the one used for the meter calibration. Figure 3 shows the sensor calibration setup for which the sensor was placed on a fixture where flexible plastic tube was connected via one-touch connectors to the sensor and de-ionized water was used for calibration medium. The control board was connected to the sensor via a flexible cable on the input while the output was connected to a computer for data collection.

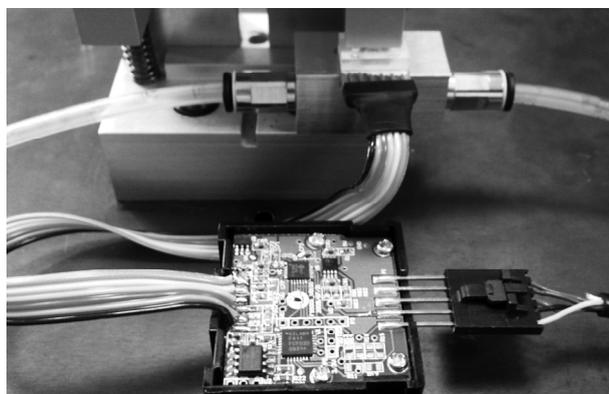


Fig. 3 Sensor calibration setup

Calibration usually is the most expensive step during the sensor manufacturing process, as it is very time-consuming if many data points have to be collected for each individual sensor.

Fortunately as the MEMS sensors are made from the process tools that are similar to those used in today's IC productions which ensure the uniformity and highly consistency from each sensor chip. Based on the manufacture database, we found that all of the sensors output similar curves that can be proximate with a fourth order polynomial. This then allows significantly reduction of the calibration data point leading to a low cost for the manufacture. Figure 4 shows the typical calibration curve, and Figure 5 is the measured accuracy against the mass flow rate indicating a typical $\pm 2\%$ performance.

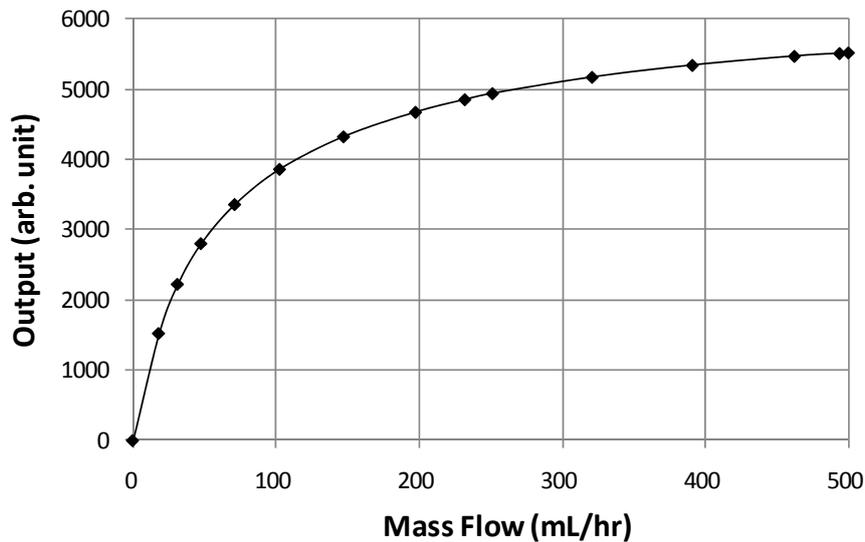


Fig. 4 Sensor output against the mass flow rate.

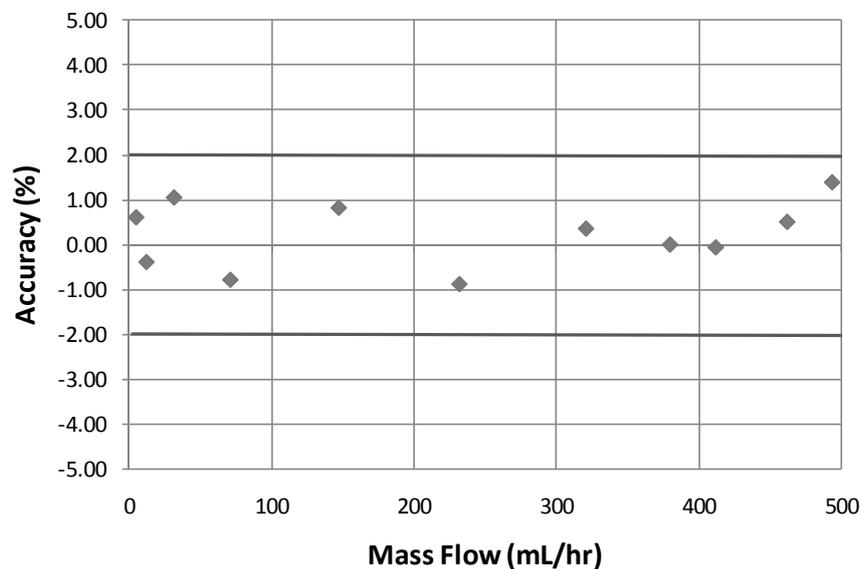


Fig. 5 Sensor accuracy against the mass flow rate.

3.2 Inlet Pressure Effects

Because of the microfluidic character, the inlet pressure of the sensor may also introduce additional variables to the sensor performance. In most cases, the inlet pressure at a practical application may differ from that at the calibration. Hence the package design should take this into

accounts. One of the solutions is to design a large reservoir buffer at the inlet. To verify this pressure effects, tests were carried out by placing a de-ionized water tank at different elevated level to simulate the different inlet pressure variations for a sensor calibrated at an inlet pressure of 2 bar. A scale instead of the Coriolis mass flow meter was used to measure the flow rate via the changes of the water weight as the Coriolis flow meter itself requires a high input pressure and has 1 bar pressure drop. The flow rate was maintained initially at 120 mL/hr while the signals from sensor were recorded via the sensor analog output against the changes of the inlet pressure.

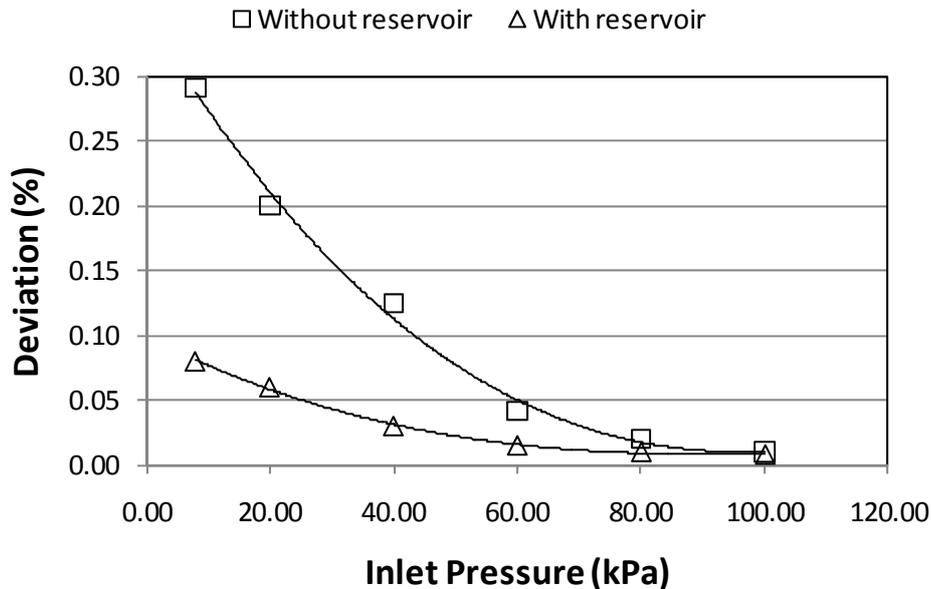


Fig. 6 Instability of flow rate with the inlet pressure variation

It can be observed from the data shown in Figure 6 that the instability occurred mostly at a low inlet pressure and the flow was stabilized with the increase of the inlet pressure. The data also clearly indicated that the reservoir would assist the stability of the flow performance.

4. Conclusion

The MEMS mass flow technology can enable the microfluidic applications while at a disposable cost. It could provide the miniature package particularly suitable for medical applications and improve the performance in the infusion delivery system.

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