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Industrialized Functional Test for Insulin Micropumps

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Abstract

We report on original industrialized functional testing methods for insulin micropumps. A specific Design-For-Test associated with the analysis of the integrated pressure sensor signal, during a specific actuation profile, allows a complete characterization of the pump functionality in few seconds. All critical failures due to fabrication and assembly create clear and specific deviations from nominal signal. The pressure sensor sensitivity coupled to the high compression ratio and the small dead volume of the micropump lead to a leak detection sensitivity of only few nl/h for water or insulin at 37°C.

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Keywords: Micropump; Design-For-Test; Functional Testing; Pressure sensor; Drug delivery; Insulin.

1. Introduction

A micropump based on MEMS (Micro electro-mechanical systems) technologies has been developed for precise open loop infusion of insulin in a CSII (continuous subcutaneous infusion of Insulin) therapy. The micropump delivers rapid- or short-acting insulin 24 hours a day through a catheter placed under the skin. Fast, reliable and low-cost functional tests of the devices are desirable for industrialization. To achieve these requirements, a specific Design-For-Test has been built and an original test method is presented here.

2. MEMS micropump and functional testing

Debiotech's MEMS micropump, based on the membrane pump principle, contains a pumping chamber with a flexible pumping membrane, two passive check valves and a pressure sensor [1]. Its schematic cross section is shown in Figure 1. A piezo actuator overdrives the pumping membrane iteratively against
two mechanical stops, inducing an accurate and repeatable stroke volume of 200 nl +/- 2%. The delivery accuracy is moreover independent from environmental conditions (pressure, temperature and humidity).

![Cross-section of the MEMS micropump showing the venting port used to open or close the valve pneumatically.](image)

**Fig. 1.** Cross-section of the MEMS micropump showing the venting port used to open or close the valve pneumatically.

Because the intended use of the device is insulin infusion for diabetes care, there is strong safety requirement for reliable functional test at the end of the production. The use of liquid is considered as destructive because of the possible contamination during test and the difficulty to dry the pump afterwards. Moreover the test cycle time with a liquid is not compatible with high volume production. The use of commercial gas flowmeters to characterize the pump is no longer relevant because of their limited sensitivity for leak detection and slow time response that is not adapted to pulsed flow.

A specific Design-For-Test is proposed to perform the functional testing: the outlet valve is made of a membrane, having a specific venting port, which can be controlled pneumatically (pressure $P_{\text{vent}}$ in Figure 1). The test method is based on the actuation of the pump while the outlet port is forced closed. During this isothermal process the relative pressure in the pump reaches about 0.9 bar according to the high compression ratio of the pump. The analysis of the pressure decay with the integrated pressure sensor characterizes the pump tightness.

![Top view (a) and side view (b) of the micropump and its piezo actuator mounted onto a substrate.](image)

**Fig. 2.** Top view (a) and side view (b) of the micropump and its piezo actuator mounted onto a substrate.
The equation (1) gives the expression of the time $\tau$ necessary to reduce the relative pressure by a factor 2 after the compression:

$$\tau = \frac{R_{eq}V_D (\ln(1+P_0/P_{max}))}{P_0}$$

The sensor resolution, better than 5 mbar, coupled to the high generated pressure and the small pump dead volume leads to a leak detection sensitivity corresponding to only few nl/h for water at 37°C. The time $\tau$ is typically about few seconds for functional micropumps.

Since the dead volume of the micropump is well controlled during production, the measurement of the compression ratio gives a good estimation of the stroke volume. An optical measurement of the membrane or actuator displacement during the dry test allows also the verification of the stroke volume and the actuator functionality.

Crackguard rings implanted into silicon are finally tested electrically during the functional test to verify the mechanical integrity of the micropump.

The Figures 2(a) and 2(b) show respectively front and side views of the micropump and the piezo actuator mounted onto a substrate. The pads for electrical connection and the vent hole are located on the same substrate side while micropump inlet and outlet ports are located on the opposite side. The vent hole in the substrate and the back-side of the outlet valve are connected by a channel. An industrialized socket to provide electrical and pneumatic contacts onto the substrate has been designed for the test.

This dry test is a true functional test since the real pumping capability is verified.

### 3. Typical data and discussion

The complete dry test protocol includes also several push-pull actuations without forcing the outlet valve closed in order to check the valve pretensions. A typical pressure profile for functional micropump at slow actuation rate is provided Figure 3(a). The inlet and outlet valve pretensions are estimated after the pull and push phases respectively while the compression ratio and the leak rate are estimated during a push phase once the outlet valve has been blocked pneumatically.

Typical pressure profiles during dry tests for micropumps having an inlet valve blocked, a valve leakage or an inverted piezo polarization are shown Figures 3(b), 4(a) and 4(b) respectively.

Industrialized dry functional test including the calibration of the integrated pressure sensor can be achieved in less than 5 seconds.
Fig. 3. (a) Standard pressure profile during functional test; (b) Pressure profile during functional test for a pump having an inlet valve blocked.

Fig. 4. (a) Pressure profile during functional test for a pump showing valve leakage; (b) Pressure profile during functional test for a pump having an inverted piezo polarization.

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References

[1] N. Schneeberger, R. Allende s, F. Bianchi, E. Chappel, C. Conan, S. Gamper, M. Schlund, *Proceedings of the Eurosensors XXIII conference, Procedia Chemistry*, 2009; 1:1339–1342.