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A nondisposable liquid flow sensor for medical applications.

Image: Sensirion AG

Digital Flow Sensors:

Reaching New Levels

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Microchips that combine sensor technology with digital signal processing on a single microchip can boost the performance and reduce the cost of measuring devices. How they can be employed in disposable applications such as liquid drug delivery and respiratory-flow monitoring is described here.

Current situation

Flow sensors are already being used in respiratory-flow monitoring. However, high cost and lack of technical options have prevented the integration of desirable features such as offset monitoring and self-test functions into disposable products for medical systems. In addition, employing gas-flow sensors in disposable products, of course, resolves the need for sterilisation.

Until now, flow sensors have not been used in drug-delivery applications, but improved safety profiles, process monitoring functions such as detection of clogging or bubbles and electronic recording of delivered volumes are increasingly being requested. In addition, improved dosing accuracy could be achieved by using feedback for active control of pumping and dosing processes.

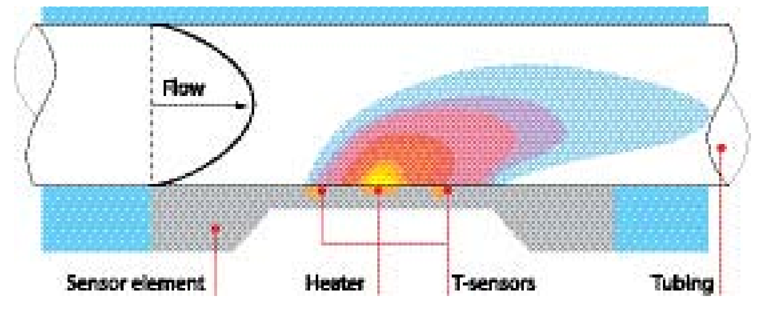
New solutions for both of these applications require flow sensors that allow flow rates to be measured accurately with high sensitivity. Furthermore, continuous measurement of flow or differential pressure over time would allow the total transported volume of gas or liquid to be calculated. Technological progress in microsensor technology now makes it possible to produce components that are smaller, cheaper and suitable for low-power applications. This article explores what this means for medical devices.

Technological progress

Today's designers can use digital CMOS[1] sensor technology, which combines microsensor technology and digital signal processing on a single CMOS microchip. Digital CMOS sensors are based on microelectromechanical systems (MEMS) technology; they offer a range of beneficial features and can be produced in large quantities. For example, digital humidity sensors employing this technology are being manufactured in quantities of millions per year for consumer applications.

A digital CMOS sensor chip for flow measurement obtains its measurement signals from a well-known type of structure (Figure 1). A miniature heating element on the microchip injects a minute, constant amount of heat into the fluid for thermal-flow measurement. The latest liquid-flow designs can obtain accuracy of, for example, 2% of the measured value using 90–300 μJ of energy per measurement. Concerns about introducing heat into the medium are thus unfounded in most cases. A pair of temperature sensors positioned symmetrically upstream and downstream of the heat source detect slight temperature differences down to 0.002 °C within milliseconds, thus providing basic information about the distribution of the caloric energy in the medium. This is the fundamental information needed to subsequently calculate the actual total flow or dosed volume. Additional features such as lower power consumption

Figure 1: Operating principle of thermal flow measurement.



because of minimised thermal capacity, measurement response times of <20 ms for liquid flow and <2 ms for gas flow, and repeatability of approximately 0.6% of the measured value are possible.

On-chip digital signal processing

Sensor signals must be processed in an appropriate manner to maintain high signal quality and to allow them to be integrated into user systems. For most sensors, the essential functions necessary to achieve the high performance required by an application are amplification, digitisation, linearisation and temperature compensation. Depending on the MEMS sensor generation (see Table I), these functions can be integrated into the sensor chip to provide greater immunity to electromagnetic interference and signal quality (for example, dynamic range of 1:100 with an accuracy of 3% of the measured value). The structure of this type of chip can be seen in Figure 2.

Characteristic sensor data required for linearisation and temperature compensation during operation is generated by a calibration process during production. For disposable sensors, it is essential that the calibration data can be stored and processed inside the sensor component to eliminate the need for calibration by the user (patient, nurse or doctor). That is possible in the fourth-generation MEMS sensors. These chips contain the full intelligence and memory required for on-chip signal linearisation, temperature compensation, and self-test algorithms. The fourth-generation sensor chip for flow measurement applications is approximately 2 × 3 mm in size. Achieving this level of integration means a full single-chip solution is possible. Using standard chip technology makes it possible to economically produce these sensor chips in standard semiconductor facilities. As a result of the chip's low energy consumption, an attractive option is to provide these sensors with radiofrequency-identication- (RFID) like on-chip circuitry for wireless communication and/or wireless power supply. This circuitry can, for example, comprise a demodulator and rectifier for receiving power and data via a coil antenna, as well as a modulator and driver to send back data via the same antenna.

Liquid drug delivery

Flow monitoring and feedback control in future drug delivery systems will benefit from liquid-flow sensors that allow flow rates to be measured accurately down to 200 pL/min depending on the application. In addition, thermal MEMS liquid-flow sensors can detect bubbles utilising the difference between the thermal properties of the gas and the liquid (US patent 6763710) and the response times of <20 ms.

Full isolation of the liquid medium from its environment is often required. The packaging enables the microchips to measure flow through the walls of thin-walled polyetheretherketone, steel or glass channels with full media isolation (Figure 1). Simple, straight capillaries with inside diameters ranging from 20 µm to more than 1 mm are currently being used as flow channels for sensors based on this principle, with the sensor chip bonded to the outside (Figure 3). This can be done while maintaining heating power at a low level of, for example, 2.5 mW, depending on the application.

Other issues also become important when the drug delivery system is viewed as a whole. A sensor-actuator combination is needed for many applications and the actuator must be combined with the sensor

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Table I: MEMS sensor generations represent the progress made in microsensor technology and can be characterised as follows:

- **First generation:** MEMS sensor element usually based on a silicon structure, sometimes combined with analogue amplification on a microchip
- **Second generation:** MEMS sensor element combined with analogue amplification and an analogue-to-digital converter on a single microchip
- **Third generation:** Merging the sensor element with analogue amplification, an analogue-to-digital converter and digital intelligence for linearisation and temperature compensation on a single microchip
- **Fourth generation:** The same features as a third-generation MEMS sensor, plus memory for calibration data and temperature compensation data.

Figure 2: A highly integrated digital flow sensor chip.

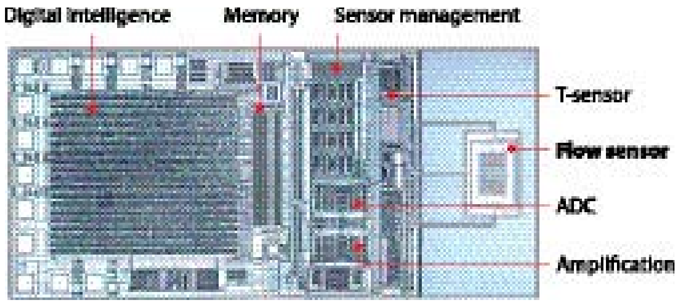
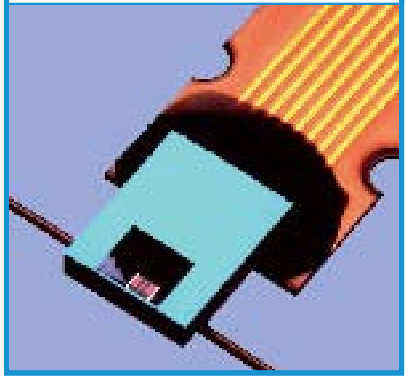


Figure 3: Sensor chip measuring flow media isolated through the wall of a capillary.



➔ and additional components to form a microsystem such as a disposable dosing unit. The demand for microvalves (active and passive) and micropumps that can be produced in high volume at low cost will thus increase significantly in the future.

Gravimetric drug delivery is a good candidate for initial applications, because it can be improved by using electronic feedback to control the delivered drug dose. With this sensor-system approach, additional features such as electronic recording capability become automatically available. A disposable valve or reusable pinch valve (with disposable tubing) can be used as an inexpensive actuator.

Respiratory flow monitoring

Gas-flow sensors have been used for a long time to measure volume flow in a bypass channel. Some medical device manufacturers have replaced static differential pressure sensors with gas-flow sensors to achieve higher sensitivity at low flow rates (such as in neonatal ventilation) and eliminate sensitivity to vibration. Unfortunately, conventional calorimetric measurement methods such as the hot-wire method or mass-flow sensors using temperature sensors and a heat source are sensitive to dust deposits and high humidity.

The first step in resolving these issues is to reduce the amount of flow going through the mass-flow sensor in the bypass to thereby reduce the risk of dust deposits. The high resolution at low flow required for measuring the low bypass flow can be achieved by amplifying and digitising the signal on the chip (second-generation MEMS sensor). Additional construction features such as a smooth surface, glass coating and the absence of bond wires in the flow channel make the mass-flow sensor robust with respect to deposits and high humidity.

As a second step, integration of a temperature sensor on the mass flow chip provides better performances over a temperature range of 0–60 °C without any additional electronics (third-generation MEMS sensor). The temperature information can also be used in combination with a digital humidity sensor chip to monitor the dew point and avoid condensation in the tubing leading to the patient.

The third step is on-chip integration of the calibration data (fourth-generation MEMS sensor) and improved signal processing performance. Integration of the calibration data memory on the sensor chip to avoid the need for new user calibration every time a sensor is replaced is a major requirement for disposable applications. The increased speed of fourth-generation MEMS flow sensors allows measurements to be made at the rate of 1/ms, which makes it possible to detect highly dynamic signals with high frequencies such as snoring or resonances in the blower. Last but not least, improved signal processing capacity combined with a digital interface make important on-chip self-test functions possible for disposable products; these functions include detection of deposits on the flow sensing element, offset compensation, and a check sum (redundancy check) for every measurement. Finally, cost reduction thanks to the small size of the chip and the standard CMOS manufacturing process now make it possible to use gas-flow sensors in disposable applications.

Future prospects

Tiny, calibrated, fully digital sensor chips will be part of disposable products in the future. This technical development changes the ground rules for the design of disposable drug delivery systems. Ultra-small liquid volumes down to the nanolitre range can now be monitored and dosed at a lower cost with better accuracy.

The field of respiratory applications will benefit from the stability of the new sensors for measuring small-volume flows in a humid environment with temperature variations. The small size, low-power consumption and reduced manufacturing costs of these devices will allow calibrated flow sensors to be integrated into single-use patient masks and tubing. Because production of these tiny chips is based on CMOS semiconductor technology, they can be economically manufactured in high volumes.

Technological hurdles on the way for disposable products are packaging and calibration during production, as well as communication and power supply. The transfer of know-how from other mass-product applications will assist in overcoming these hurdles.

The scope of technical options to increase safety and accuracy and add supplementary electronic monitoring and control features has been enlarged significantly with calibrated single-chip solutions. Because of the low power consumption and short power-up times of the sensors, battery-operated systems will benefit and wireless RFID systems are also possible. The disposable portions of medical systems will incorporate more functionality into future products. That will make it possible to improve safety and performance while reducing investment and maintenance costs for reusable devices. Impressive sensor performance makes competitive design solutions possible.

Reference

1. CMOS is a standard fabrication technology for integrated circuits. CMOS chips, commonly referred to as semiconductor chips, silicon chips or computer chips, are widely used in almost all areas of everyday life. The best example of a CMOS chip is the Intel Pentium processor in the PC.

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