Designing Cutting-Edge Wearable Medical Devices

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As healthcare moves out of hospitals and becomes more integrated with peoples' lives, medical devices are evolving from portable equipment to wearable devices that are meant to be used continuously for extended periods of time. These new devices present designers with many new challenges. This article examines some of those challenges and offers examples of how they can be met.

Medical devices that are worn on the body are not new. Most people are familiar with wearable products, such as nicotine patches and patches for motion sickness. These devices laid the groundwork for a new generation of electronic products. One member of this new generation is the iontophoresis patch.

Infusion Drug Therapy
Iontophoresis uses an electrical current to enable the infusion of a drug through the skin. The transdermal drug is ionized, dissolved in an aqueous solution, and applied to an electrode in the patch. This specially formulated, ionized compound can then be moved through the skin via DC current (Figure 1). Most patches used today are meant to be worn for anywhere from a few minutes to a few hours, depending on the drug and the condition being treated.

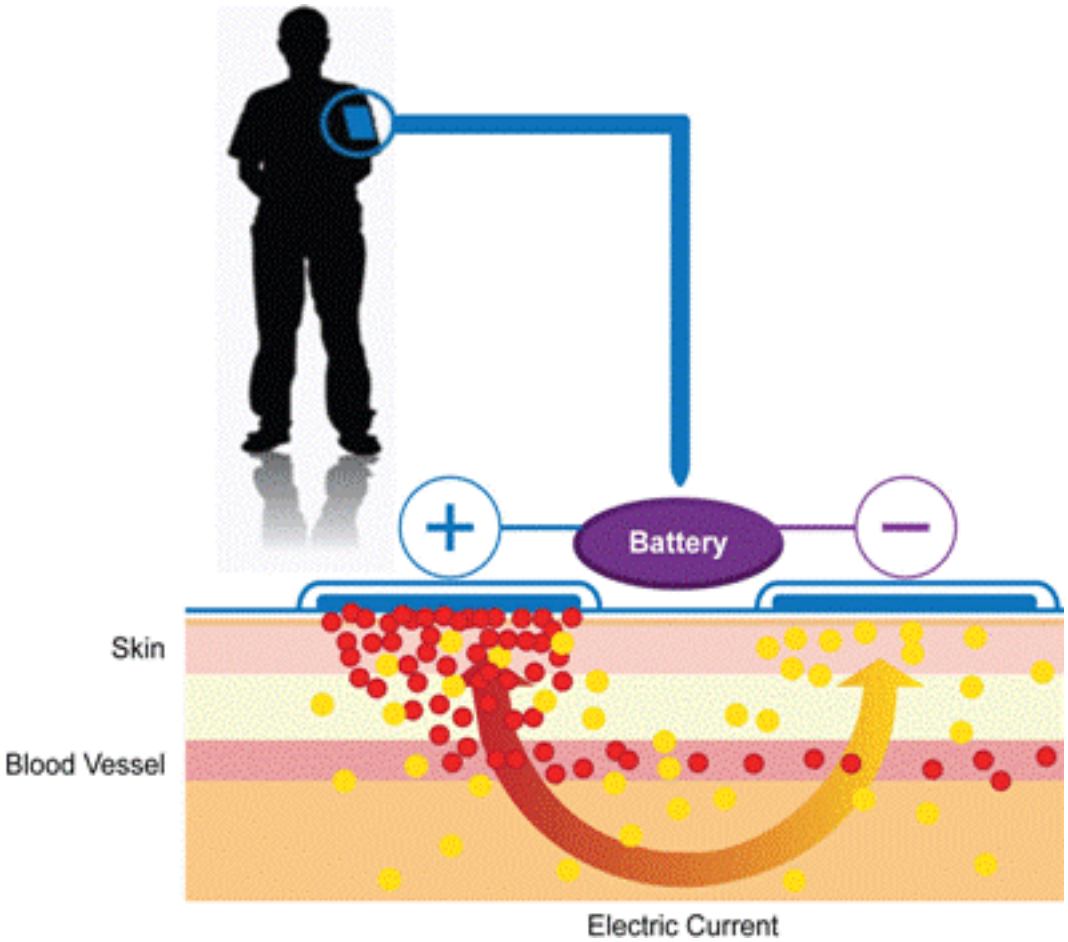

Figure 1: Typical iontophoresis operation

There are several advantages to iontophoresis. First, the medicine can be locally dosed at very high levels rather than being distributed throughout the entire body, which occurs with syringe injections. This local administration can result in improved efficacy and reduced side effects.

Advances in electronics technology, such as switched mode power-supply design—along with cost-effective, high performance MCUs—have made the production of low-cost, single-use dispensers for these drugs possible. Self-applied iontophoresis has already been used by many consumers to deliver medicines for many conditions, including headaches, cold sores, and wrinkles.

Some of the biggest challenges that designers face when creating devices such as iontophoresis patches are that the critical electronics are in the wearable portion of the device, which is meant to be used once and then thrown away. This scenario creates intense pressure for the patch electronics to be small and inexpensive. Also, since this is a small, disposable item, battery cost and energy capacity impose further constraints on the design. Finally, the design needs to be easily modified for additional features, such as changes in the medication dose and duration.

To infuse the drug through the skin, the device must produce sufficient voltages to drive the current level needed for the specific infusion dose rate, and for the required duration period. A working design for a small, cost-sensitive iontophoresis

device can be as simple as a DC/DC boost converter to drive a controlled current through the skin, along with a microcontroller (MCU) to control the converter.

The boost regulator is used to step up the voltage from a low-voltage battery to sufficient levels for passing the required current through the skin. Inexpensive Lithium coin or alkaline cell batteries can be used to provide power to the patch electronics.

Meeting the requirements for both cost and functionality calls for a MCU that is small yet highly integrated. Microchip's [1] 8-pin, 8-bit PIC12F1822 MCU is used in these devices and meets the design integration requirement, with an internal 10-bit ADC, fixed voltage reference, comparator, PWM, hardware timers, and EEPROM. The fixed voltage reference eliminates the need for a regulator or an external reference, and keeps the design to an 8-pin MCU in order to lower the cost and reduce board size.

Long-Term Monitoring

Figure 2: Fertility monitor reader and sensor

Innovation in electronics technology is enabling the development of medical devices that are intended to be worn on the body for long periods of time, in order to improve the quality of life and the quality of healthcare for patients. Continuous glucose monitors and wearable cardiac-event recorders are two well-known examples of such devices.

A unique example of a device that takes long-term use to a whole new level is the ovulation prediction system. These devices are used by women who want to maximize their chances of conceiving. One such wearable device is the DuoFertility-brand fertility monitor (Figure 2). This device is made by Cambridge Temperature Concepts [2] and it embodies a number of attributes that are essential to long-term monitoring systems, in general.

The ovulation process in a woman’s body correlates to minute changes in her basal body temperature. Accurately measuring those temperature changes over multiple monthly cycles can help to estimate the day of ovulation.

While a continuous glucose monitor may be designed to operate for up to a week, the sensor on this fertility device continuously measures body basal temperature for up to six months. The device uses this information to predict, up to six days in advance, when ovulation will occur. Constantly monitoring minute temperature changes eliminates the many variations that occur when women have to take their temperature manually.

One challenge that designers of this type of device face is creating a physical form factor that can be comfortably attached to the body for months at a time. In this case, the solution was to make a two-part system. The coin-sized sensor unit attaches to the user's body with a biocompatible adhesive patch. The handheld reader unit analyzes the data and allows the user to transfer that data to medical professionals for further analysis. This functional partitioning enabled the body-worn sensor to be as small and light as possible. A block diagram of the monitor’s sensor and reader is shown in Figure 3.

Another challenge is to anticipate all of the environments that the user will be in, and the activities in which they may engage. With a usage timeframe of months, a wearable device must accommodate a wide range of conditions, including sleeping, exercising, showering or even snow skiing. In this case, the design of the sensor and its packaging had to make it possible to take precise temperature measurements regardless of whether the sensor is open on one side or covered by the user's arm. The designers solved this problem by using a pair of matched thermistors. They measure the temperature and the heat flow from one side of the sensor to the other, making the sensor accurate to a few thousandths of a degree. In addition, the user’s movement is taken into account by incorporating an accelerometer in the sensor design.

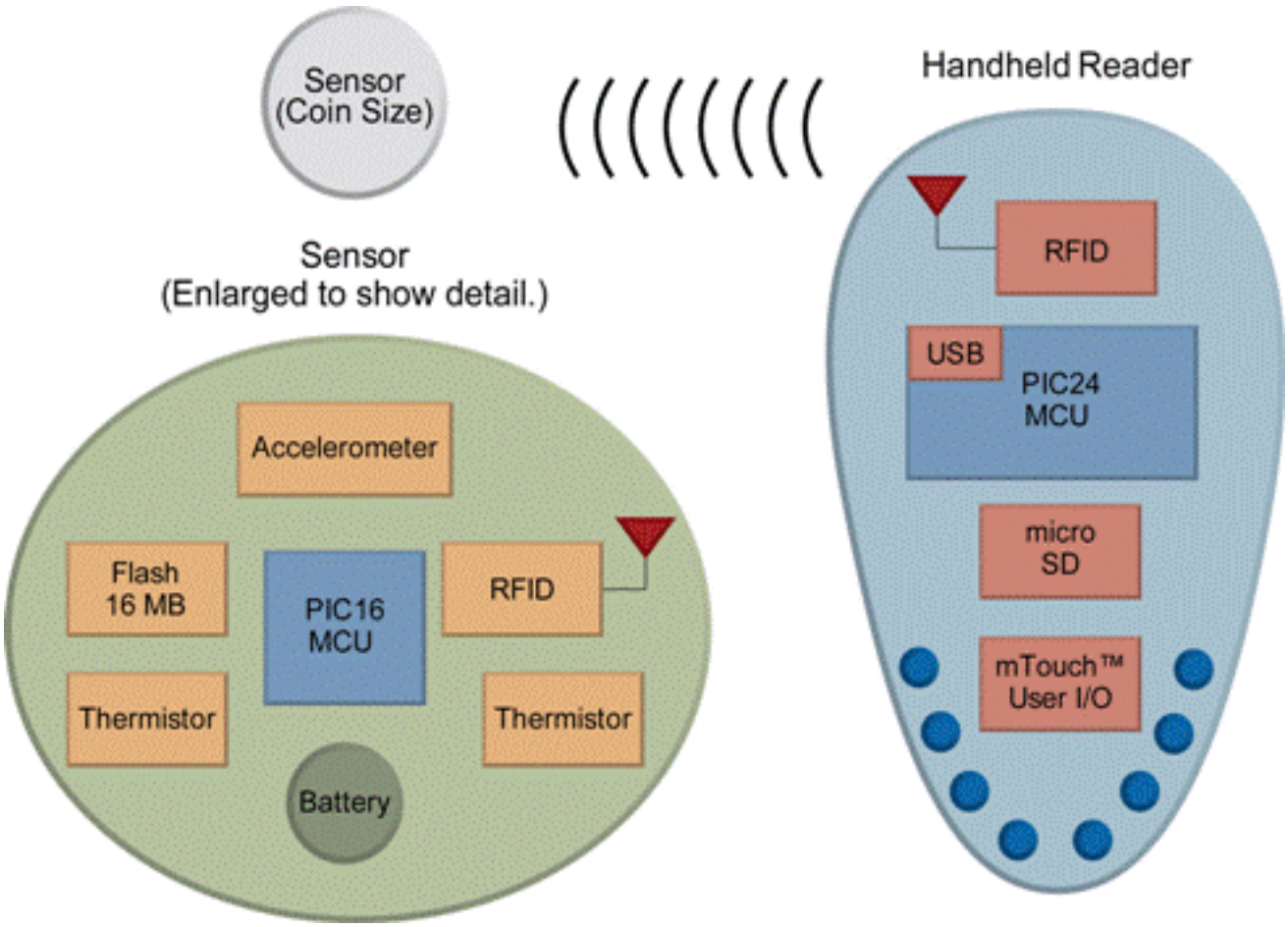

Figure 3: Block diagram of sensor and reader

Body-worn electronics have to be very small, which means the volume available for batteries is very limited. So, another challenge of the sensor design is to keep the power consumption extremely low. The designers of this sensor used an 8-bit PIC16F886 MCU in order to minimize the sensor's current consumption. Minimal current consumption was achieved by using the MCU's ultra low power wake-up feature.

When it's time to take a reading, the sensor powers up, takes a measurement, and then returns to sleep mode—all in less than 1.0 mS. This short wake-up time enabled the device's designers to achieve average power consumption of less than 1.0 µA, and a battery life of six months, using a small CR1216 Lithium coin-cell battery.

Another challenge is to transfer the measured data. This sensor module sends data to the reader using a modified RFID protocol, wherein communication is initiated by holding the reader near the sensor. This data transfer requires higher power consumption than measuring the data, so the designers minimized current draw by holding the sensor's temperature readings in 16 megabytes of stand-alone Flash. This allows reader data uploads to be spaced a few days apart.

Since the data collected by a long-term sensor may need to be analyzed by a trained person, creating a straightforward and cost-effective way to transfer the

measured data to a PC and communicate over the Internet is yet another important design consideration. The second part of this device, the handheld reader, is utilized for that purpose.

The reader transfers the data to a PC via the on-chip USB peripheral inside Microchip's 16-bit PIC24FJ256GB106 MCU with nanoWatt Technology. The user can enter additional data, via front-panel buttons that are implemented using the MCU's internal Charge Time Measurement Unit and mTouch Capacitive Touch technology.

Communication from the device manufacturer to the reader allows for refinement of the ovulation prediction. The same capability can allow remote reconfiguration of the MCU. With this flexibility, the manufacturer can run diagnostics and send software updates to the monitoring system.

Conclusion

As innovation continues in the fields of biology, physiology, chemistry, and electronics, wearable medical devices that are meant for long-term use will create new diagnostic and therapeutic options for even more illnesses and conditions.

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