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DEVELOPMENTS in
Continuous Glucose Monitoring

The Potential Use of Radio Frequency Identification Devices for Active Monitoring of Blood Glucose Levels

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Abstract

Imagine a diabetes patient receiving a text message on his mobile phone warning him that his blood glucose level is too low or a patient's mobile phone calling an emergency number when the patient goes into diabetic shock.

Both scenarios depend on automatic, continuous monitoring of blood glucose levels and transmission of that information to a phone. The development of advanced biological sensors and integration with passive radio frequency identification technologies are the key to this. These hold the promise of being able to free patients from finger stick sampling or externally worn devices while providing continuous blood glucose monitoring that allows patients to manage their health more actively. To achieve this promise, however, a number of technical issues need to be addressed.

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Background

The most common method of monitoring blood glucose levels (finger sticks) relies on active patient participation and adherence to a schedule of monitoring activity. While newer glucose meters require smaller samples and are becoming easier to use, they are still "passive" devices that require the patient to take and test blood samples.

New continuous blood glucose sensors require a cannula to be implanted in the abdomen or arm connected to an externally worn monitor or communications device. While this eliminates the need for patient sampling, they are invasive and require the patient to carry an external glucose monitor.

The optimal solution would be one whereby the patient is not required to carry a separate monitoring device and which requires neither finger sticks nor an implanted cannula.

A Brief Introduction to Radio Frequency Identification (RFID)

Radio frequency identification is not a single technology. Rather, the term encompasses a wide range of devices with varying degrees of functionality, capabilities, range, and performance.

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Abbreviations: (FDA) Food and Drug Administration, (HF) high frequency, (LF) low frequency, (NFC) near field communication, (PDAs) personal digital assistants, (RFID) radio frequency identification, (UHF) ultrahigh frequency

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A basic RFID system is composed of a tag to carry data and a reader (interrogator) with an antenna. The tag is made up of a chip (an integrated circuit) attached to an antenna.

The most common devices today operate at different radio frequency ranges: low frequency (LF) at about 128–135 kHz, high frequency at about 13.56 MHz, and ultrahigh frequency (UHF) at 860–960 MHz. Each frequency range has unique characteristics in terms of RFID performance. A simplified way of understanding the performance and limitations of RFID systems is to categorize them relative to each other (see **Table 1**). Because different manufacturers' products have different capabilities, **Table 1** shows only general characteristics.

Table 1.
General RFID Performance Characteristics

Frequency	Data rate	Range	Affected by liquids/metals	Ability to penetrate walls, etc
LF (128–135 kHz)	Slow	Near contact to 35 cm	Very little	Very good
HF (13.56 MHz)	Moderate	Near contact to 120 cm	Somewhat	Good
UHF (860–960 MHz)	High	Long (1–4+ m)	Yes	Moderate

One additional differentiation is whether the tag contains a battery. Passive tags, those without batteries, rely solely on the power of the incoming RF signal to generate their response. Those with batteries, active tags, typically use the battery to boost the return signal. Battery-assisted passive tags, however, have a battery but typically only use it to power sensors, maintain histograms in memory, or perform other internal tasks.

Limiting Considerations

Radio frequency transmissions can be affected adversely by the presence of liquids or metals. Radio signals are attenuated (changed) or absorbed by liquids and metals. This issue is significant when considering RFID for use with patients. UHF is the most affected by this but has the longest range of commonly used tags. HF is not as affected significantly but has an intrinsically shorter range. LF tags are least affected and can, in fact, be implanted subcutaneously and are readable in very close proximity to the skin but require careful alignment of the reader to tag orientation.

Therefore, for implanted RFID tags, LF is the obvious choice. However, HF and even UHF can be effective for tags that are external to the body. Currently, the range of these frequencies may be less than achievable in other applications but can be entirely acceptable for glucose monitoring.

There is some concern, primarily in Europe and Japan, about potential health risks of exposure to high levels of HF and UHF radio waves. Low power settings and intermittent interrogation of an RFID tag mitigate these potential risks. Certain LF signals can also interfere with implanted medical devices such as pacemakers and cardio-defibrillators. While further testing and risk mitigation are indicated, it is anticipated that the signal strength for any RFID device used for monitoring patient condition remotely will be fairly low and, therefore, should not be a concern when using RFID for blood glucose monitoring.

Radio frequency identification devices operate within the health and safety limits set by international bodies. However, in light of recent reports of potential adverse effects on implantables and medical devices, further studies on the potential effects of RF on implantables, medical devices, and biologicals—and examination of possible mitigation techniques—are being initiated.

Positive Considerations

Radio frequency identification offers the possibility of relaying data from glucose monitors to an external reader without the need for leads or other invasive monitoring methods. Both implantable and noninvasive monitors that are RFID enabled are under development.

Radio frequency identification readers have already been incorporated into mobile phones, personal digital assistants (PDAs), and similar consumer electronics. Mobile devices are becoming ubiquitous and would be able to provide the platform for blood glucose reporting.

Near field communications (NFC), intended for very short range applications, is gaining wide acceptance, particularly among the manufacturers of mobile devices. NFC uses 13.56 MHz at a very low power level and relies more on magnetic fluctuations than on radio frequency communication. Use of NFC may ameliorate any concerns about human exposure to RF with blood glucose monitoring.

There is promising research in thin film battery technology, including the possibility of batteries recharged by motion or body heat. Such batteries could provide an extended range for active or battery-assisted passive tags that would have an extremely long life.

The Vision

Near Term Vision

A blood glucose sensor-enabled LF RFID tag would be implanted subcutaneously in a convenient but "private" location such as the inside of the upper arm. (This location would help prevent any surreptitious or unauthorized reading of the tag.) VeriMed is reportedly still working on developing a glucose monitor integrated with its implantable, LF RFID tag. The VeriMed RFID tag is implanted using a large-gauge veterinary needle and requires no surgery and no external leads or connections. This is the same RFID tag used for companion animal identification under the Digital Angel brand. The sensor would sample blood glucose levels and report the level via the RFID tag whenever queried by a LF interrogator in a mobile phone, PDA, or similar device.

Software in the mobile device would, depending on configuration, display the reading as do current meters or react only to either high or low levels or sudden trends. The patient would acknowledge (cancel) this type of alert and take appropriate action.

A mobile device could also theoretically maintain a histogram of blood glucose levels and display them for the patient to review. Optimally, the patient could annotate this histogram for future reference (such as activity, meal times, or other relevant data). This histogram could be stored on the mobile device or transmitted via the Internet to the patient's home computer or health care professional.

This vision, however, does require the patient to routinely interrogate the tag with the mobile device.

Intermediate Term Vision

Recent developments may have already made the near term approach with an implantable sensor obsolete. A minimally invasive blood glucose sensor that measures interstitial fluid has been developed by Georgetown University and SAIC. This is an outgrowth of a remotely read temperature sensor that is worn on the skin (see **Figure 1**).

Figure 1. Intermediate phase with "patch" communicating only to mobile device. Illustration courtesy of Gentag, used with permission.

The RFID company Gentag is working with SAIC to incorporate a passive RFID device with a unique identification number and geo-location capabilities with this glucose sensor. The goal is to produce a thin, flexible device ("patch"), similar to a nicotine patch, incorporating both the sensor and the RFID transmitter that will sample blood glucose levels and transmit that data, securely, to the patient's mobile device. Initially, this device will be a passive tag and use the energy of interrogation by a mobile device to power its response to the monitoring device. This will still require the patient to initiate reading.

Mobile phone manufacturers are currently integrating a variety of NFC, HF, and UHF RFID readers into their devices. While there is no clear indication on which reader(s) will become standard, add-on devices such as shown in **Figure 2** would be able to provide any

Figure 2. Temperature sensor being read by a specially equipped mobile device with an add-on RFID interrogator (right side of device). Illustration courtesy of Gentag, used with permission.

necessary reader technology. This solution also depends on the development of a skin "patch" glucose sensor and Food and Drug Administration approval for any such device.

Longer Term Vision

Ideally, a longer range RFID tag will be developed to provide the patient with automatic, continuous monitoring on a mobile device. Extending the range of the "patch" to enable automatic monitoring via a wireless network in the home or via a cellular network outside the home would be the next step (**Figure 3**).

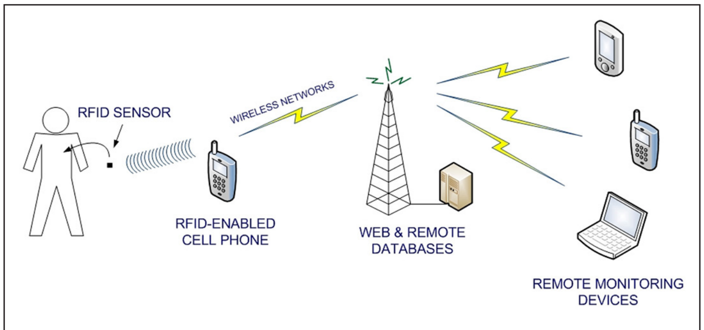

Figure 3. "Patch" communicating via a cellular or wireless network. Illustration courtesy of Gentag, used with permission.

As with the near and intermediate term visions just given, the "patch" would communicate with a patient's mobile or home device. Also, as described earlier, the system would provide a report or trigger an alert if necessary. If the patient does not acknowledge the alert, the mobile device could be instructed to call an emergency contact number automatically.

This type of system requires the integration of several technologies: a mobile device such as a phone or PDA with an integrated RFID reader and glucose monitoring software module, a home interrogator connected to the Internet or a telephone line, an RFID-enabled sensor "patch," and, most likely, thin film battery technology to achieve sufficient range to reach a receiving device that might be in another room. Integration with mobile service providers, health care provider, and emergency responder networks would also be necessary.

The "patch" would have to be replaced on a periodic basis. Currently, the goal is to have a passive, disposable patch that could last up to a year with sampling occurring every 15 minutes.

Benefits to the Patient

In the longer term vision, the patient would have far greater independence and convenience over existing finger stick or implanted methods of monitoring blood glucose levels. The patient would only be required to take appropriate action to correct high or low levels, freeing him or her from the necessity of developing and maintaining a testing routine. Automatic monitoring would provide a greater quality of life while providing a greater quality of blood glucose monitoring. Additionally, a geo location via a "patch" or mobile device could provide life-saving information in the event of diabetic shock.

Disclosure:

Bert Moore is the director of communications for AIM Global, the international trade association representing automatic identification and mobility technology solution providers. AIM Global's Web sites are *www.aimglobal.org* and *www.rfid.org*.