

Embedded Microelectronic Chip Enhances RFID Tracking

With FDA's recent policy decision to require linear bar codes on the labels of thousands of human drugs and biological products, integrating a tracking system into the coding to address patient compliance issues may be just around the corner. One of the most popular emerging technologies for this application, radio frequency identification (RFID), however, has raised questions about patient confidentiality, since conventional RFID systems also capture patients' personal information, which can be easily accessed by various readers.

To help address this issue, Cypak (Stockholm, Sweden) has designed an electronic data capturing system aimed at monitoring patient activity more securely. The "Intelligent Pharmaceutical Packaging" (IPP) system works similarly to current

RFID technology solutions but uses a dedicated scanner combined with encrypted coding within a microelectronic sensor chip embedded in the packaging to ensure privacy. "Whereas current RFID technology can be read at a distance," explains Stina Ehrensvärd, Cypak founder and director of marketing, "our technology requires actual contact, making it safer and more secure."

The IPP sensor chip is about 0.3 mm in height with 32 kilobytes of memory capacity (see Figure 1), offering greater functionality than current RFID technology solutions. The chip, which Cypak began developing in 1999, is now being used in patient trials. The company's first design, recently licensed to MeadWestvaco Healthcare Packaging (Stamford, CT), is being applied to tablets in a blister pack (see Figure 2).



Figure 1: Cypak's microelectronic sensor chip is about 0.3 mm in height and can store 32 kilobytes of memory.

Although the chip provides the "intelligence," a simple technique is used to communicate the state of the package to the chip. "It's an old technology that's been reinvented," says Ehrensvärd. Each tablet within the blister pack has its own line (or circuit) printed on the packaging using conductive graphite ink as part of the normal manufacturing process. The circuit is directly connected to the chip, which

monitors any event that occurs within the packaging that "breaks" the circuit—such as when a patient pushes out a dose. A clock inside the chip monitors and records the time that an event takes place.

According to Ehrensvärd, one of the major challenges in developing the packaging was the need to form a foldable package without breaking the circuits in the process. "It took a lot of time to design a foldable book," notes Ehrensvärd, "but each individual tablet is linked to a circuit, as opposed to one circuit for all the tablets, increasing the preciseness of the data."

IPP's scanner can be plugged into any computer with a USB port and reads the data when the package is placed directly onto it. Data can then be read on screen, printed, or sent over the Internet using a Web-based data management tool. Information can be viewed and exported in a variety of file formats (i.e., Microsoft Excel). "The core components to integrate this technology cost about \$1 per package in large quantities," says Ehrensvärd, "but when you're dealing with high-quality pharmaceuticals, a few dollars is not a large expense."



Figure 2: Cypak's first Intelligent Pharmaceutical Packaging (IPP) design.

The IPP system also incorporates additional features such as a temperature sensor that can alert a patient when the product is not being stored properly. The temperature sensor is mounted on a sticker integrated into the packaging. IPP is also capable of performing digital signing of information and encryption, which ensures security and privacy when exchanging data over the Internet. This is because each IPP is pre-programmed to automatically deliver information directly to its associated database, thereby eliminating outside user input and ensuring patient confidentiality.

Another function is a printed questionnaire panel on the packaging, which gives the patient the option to provide feedback by pressing on the pack to respond. Programmable reminders can alert the patient to take a dose or respond to a question, which can be helpful in clinical trials. "One reason the pharmaceutical industry typically takes a long time to develop new drugs is because they're not getting accurate information quick enough. We believe this could be a good instrument to speed up the development time," says Ehrensvärd.

-Doreen R. Coppola